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REAUTHORIZATION OF THE NATIONAL BONE MARROW REGISTRY

HEARING

BEFORE THE

COMMITTEE ON LABOR AND HUMAN RESOURCES UNITED STATES SENATE

ONE HUNDRED FIRST CONGRESS

SECOND SESSION

ON

EXAMINING PROPOSED LEGISLATION AUTHORIZING FUNDS FOR THE NATIONAL BONE MARROW REGISTRY OF THE NATIONAL INSTITUTES OF HEALTH

MARCH 21, 1990

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REAUTHORIZATION OF THE NATIONAL BONE MARROW REGISTRY

WEDNESDAY, MARCH 21, 1990

U.S. SENATE,
COMMITTEE ON LABOR AND HUMAN RESOURCES,
Washington, DC

The committee met, pursuant to notice, at 10:17 a.m., in room SD-430, Dirksen Senate Office Building, Senator Edward M. Kennedy (chairman of the committee) presiding.

Present: Senators Kennedy, Metzenbaum, Mikulski, and Kassebaum.

OPENING STATEMENT OF SENATOR KENNEDY

The CHAIRMAN. We will come to order.

We first of all apologize to our witnesses, but we had a vote just a few moments ago and we are going to have an additional series of votes. So we are going to try to move the hearing along as rapidly as possible.

Our primary interest this morning is hearing from some of our witnesses whose lives and the lives of those whom they love have been so affected by the inadequacy of public policy in this particular area of bone marrow transplants. So today's hearing deals with bone marrow transplants and the procedures for matching donors with recipients so that this medical miracle can be available to all who need it.

To people suffering from leukemia and aplastic anemia and other diseases, a bone marrow transplant can mean the difference between life and death. In contrast to matching blood types, finding a suitable donor for a bone marrow transplant is much more difficult. The first place we look is in the patient's own family. If no suitable family donor is found, the only other hope is to find a compatible donor from the public at large.

Until recently that task had been virtually impossible. But two new major registries now exist where patients can look for possible donors: the National Bone Marrow Registry, operated under contract with the National Institutes of Health; and a private entity called the American Registry.

All too often, however, the necessity for a life-saving bone marrow transplant becomes a race with death as courageous families desperately seek suitable donors through emergency appeals to the public at large. Nearly 2,000 bone marrow transplant operations are performed a year, and 9,000 Americans are now waiting for a suitable donor. Few of these cases receive dramatic or poign-

ant nationwide attention, but in the vast majority of cases the patients are waiting and praying in silent desperation.

It is increasingly clear that more can be done and should be done to assist these victims. Hundreds, perhaps thousands, of lives could be saved by improving our system for recruiting and typing of all ethnic groups and coordinating the searches among all the existing registries.

The first priority is to remedy the severe shortage of potential donors. The National Bone Marrow Registry has only 100,000, and the American Registry has 30,000. Because the odds of finding a suitable unrelated donor are so remote, the current registries are seriously inadequate. Even with ten times the current numbers of registered donors, some patients would still be unable to find a suitable match because they have a rare type.

However, recent estimates indicate that with 250,000 donors registered, approximately double the current number, 80 percent of the patients could find a match. The cost of reaching this goal is $14.5 million.

In addition to general donor shortage, minorities are seriously underrepresented in the registry. For example, only 3,000 of the current registered donors are black. As a result, the chance of a black American finding a suitable match is extremely unlikely.

Donors are now recruited in two ways: through permanent locations, such as blood centers; or through community drives mounted to help individual patients recruit donors and defray the cost, which ranges from $60 to $75 per donor.

When Joanne Johnson, a young black college student from Silver Spring was diagnosed with leukemia in the fall of 1988, no suitable donor was available. The family organized a series of drives that registered more than 1,000 black donors. After months of searching, the family found a partially suitable donor. By that time, however, Joanne was too weak to undergo the surgery, and a few weeks later she died.

Allison Atlas has leukemia. Through her family's tireless efforts, more than 20,000 names have been added to the national registry, at a cost to the family and supporters of over $1 million. So far, Allison has not found a donor for herself, but because of her courageous struggle, 14 donors have been found for other patients. Allison's father, Alvin Atlas, is with us today and will tell us about his experience.

All of us who have heard about these dramatic cases are touched by the way families and communities come together and work together for the benefit of those in need.

But we also have to ask what kind of health care system do we have when individuals faced with life-threatening illnesses and families under enormous emotional strain are forced to conduct their own public campaigns to find the help they need? What kind of health care system do we have when information about all possible donor sources is not made routinely available to all patients searching for an unrelated donor?

In legislation reauthorizing the National Bone Marrow Registry, the committee will be addressing these questions and the problems of the current bone marrow system. Appropriations for the registry for fiscal year 1990 are $3.7 million. Of that amount, only $400,000

was specifically allocated to typing the blood of possible donors. Those funds for typing have clearly been insufficient in light of the overwhelming need and may have now been exhausted. A much more substantial appropriation for this is warranted for fiscal year 1991. I intend to work with the Appropriations Committees in Congress to see that it is provided.

In the meantime, more must be done now to help desperate families urgently seeking donors. I call on the Department of Health and Human Services to reprogram $4 million for typing of potential donors. This sum would add over 25,000 to the registries and should be targeted especially on the minority communities.

I welcome our witnesses here today and look forward to their testimony.

Our first panel consists of three congressional Members who have each had a long-time interest in the issue of bone marrow transplant. Senator Al Gore was a major player in the development of the original organ transplant legislation. He has testified frequently before our committee on these issues, and we have always valued very highly his comments and his work. He has continued to be deeply involved in the ongoing issues of the program as well as with the National Bone Marrow Program.

Congressman Vic Fazio has both a professional and a personal experience with the issue of bone marrow transplants. His interest in the program recently led him to request a report by the Office of Technology Assessment on unrelated bone marrow transplants from the patient's perspective. And we welcome very much his presence here today.

Congressman Bill Young has also had a unique vantage point on the National Bone Marrow Transplant Program as a member of both the House Appropriations Committee on Defense and the Subcommittee on Labor and Human Services. Congressman Young has been involved in the program since it was first established at the Navy and later when it was moved to the Department of Health and Human Services.

With two good members of the House Appropriations Committee on Health, I think there may be some good news for families, and Senator Mikulski, who will be here shortly, is on the Senate Appropriations Committee. I think we will have some more hopeful news.

I will ask, Senator Gore, if you would be good enough to start off.

STATEMENTS OF HON. AL GORE, A U.S. SENATOR FROM THE STATE OF TENNESSEE; HON. VIC FAZIO, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA; AND HON. C.W. BILL YOUNG, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF FLORIDA

Senator GORE. Mr. Chairman, I appreciate your courtesy in letting me go first even though you have two House appropriators here at the witness table. [Laughter.]

Six and a half years ago, when I was a Member of the House working with Vic Fazio and Bill Young and others, I had the opportunity to work on the issues related to transplantation, and I particularly enjoyed working with you, Mr. Chairman, and the

other members of this committee in the effort to enact historic legislation.

I am still proud to have played a part in that effort and look forward to the opportunity to work with you again later this year as we continue to improve that system of matching organ donors and recipients.

The situation we face now to some may appear remarkably similar to the circumstances we faced back in 1983. The names have changed. Today we pray for Allison Atlas and mourn JoAnne Johnson, even as we recall the joy that we felt when Jamie Fiske received a donor organ and the sadness we felt when Brandon Hall did not receive one in time.

But while the parallels are indeed clear, painfully clear, the challenge we face now is actually a very different challenge. Six and a half years ago we were surprised by the rapid progress doctors were making in solid organ transplantation. Our laws and institutions simply had not kept up with dramatic scientific advances, and as happens here too often, we found ourselves struggling to catch up. At the time, a familiar refrain was heard: "There ought to be a law." But there wasn't a law. Families were forced to do whatever they could to find a donor, while Congress struggled to help.

Well, today we are going to hear about a new type of transplantation, unrelated bone marrow, and again we will hear the emotional pleas of families desperate to save a child's life or a mother's life or that of a sister, brother, or spouse. And once again someone will say, "There ought to be a law."

Well, Mr. Chairman, this time there is. In 1984, as we finished work on the National Organ Transplant Act, unrelated bone marrow transplants were almost unheard of. But a few scientists who had pioneered this new technology knew that was changing quickly. They predicted this day, when families would come to us seeking help, and they gave us the opportunity then to act rather than react later.

We worked with those pioneers and added an amendment to our bill that eventually established the National Marrow Donor Program. I might say that a member of your committee, Senator Mikulski, who was then a fellow colleague in the House, was instrumental in suggesting that amendment when I took the bill to the floor.

That program, now operated under the direction of NIH, maintains a growing list of almost 100,000 Americans willing to serve as marrow donors. Hundreds of patients who only a few years ago would have had nowhere to turn have received transplants as a result of searches conducted by the National Marrow Donor Program.

We need to do more. For example, it is absolutely urgent to provide an additional $4 million to help with tissue typing and donor recruitment among minorities. The chances of the average American finding a donor is one in 20,000. If, however, you are an African American or Asian American or Latin American or Native American, you might as well forget the odds. They are so small they are really nonexistent.

We have done a great deal, and I hope we don't lose sight of that as we investigate what else we need to do. But we do need to do more.

While there are many who deserve credit for the existing system, unfortunately once again the President and the Administration are not among them. His fiscal year 1991 budget ignores the pleas for help from thousands of people struggling to stay alive, from families who refuse to lose hope, and from legislators who recognize the critical need that must be met. His budget sent to the Congress seeks no additional funds for donor recruitment or tissue typing.

Mr. Chairman, as you will recall, in 1984, as Democrats and Republicans worked together in a completely nonpartisan way to enact the National Organ Transplant Act, former President Reagan and his Administration placed one obstacle after another in our path. For years, even after he signed the program into law, he simply refused to implement it. Tragically, lives were lost.

Now we have a new President and a new Administration, but we have the same old excuses. Even as we meet here today, downtown there are bureaucrats still trying to undo the original National Organ Transplant Program, and despite a painfully obvious need to do more for minority families who are in need of a bone marrow transplant, the Administration has flatly refused to help.

This President is fond of talking about his "points of light." The National Marrow Donor Program is my nomination for one of the brightest points of light. Almost 100,000 Americans voluntarily willing to make a significant sacrifice to save the life of someone they have never met, a program supported largely by privately raised dollars, millions of privately raised dollars, in fact. But for this program to really work to really serve all Americans, it needs more. It needs a coordinating, facilitating effort by the Government. Not much, but an essential part of success.

The President has said, "No." I really cannot understand that.

So, Mr. Chairman, as the statute authorizing the National Marrow Donor Program comes up for review this year, there are a number of other issues we need to explore: the consolidation of the national marrow program registry with the American Bone Marrow Donor Registry, and the refusal by many private insurers to reimburse the costs of finding a donor represent only two of the many important questions we must explore.

I look forward to working with you and the other members of the committee as we review this important and largely successful program and work toward making some changes to insure its continued success and take that success to more people whose lives could be saved. I hope the committee will join in sending a message to the White House that it is time for the Administration to change its tune on transplant policy and join the thousands of Americans who volunteer not only their time and money but actually a part of themselves to help others.

Thank you for your efforts, Mr. Chairman.

The CHAIRMAN. Thank you very much, Senator Gore. We will be looking forward to working with you as we mark legislation up. We thank you for your continued interest and your strong support on this issue.

The CHAIRMAN. Congressman Fazio.

Mr. FAZIO. Mr. Chairman and members of the committee, I am particularly pleased to participate in today's hearing on the Nation's bone marrow registry program. I want to thank you, Senator Kennedy, and your subcommittee, for your leadership once again on still another health care issue that confronts the Nation.

I first became aware of and interested in the bone marrow registry program in 1986, when the Navy brought to the attention of Congress its concerns in this area. The program sought to collect on a national basis the names of individuals willing to donate bone marrow to unrelated individuals. It also proposed a single coordinated network to facilitate transplantation of unrelated donors. I concurred with then-Senator Laxalt that the Navy's registry could serve a dual purpose by meeting the needs of the Navy in case of nuclear mishap and the needs of civilians in identifying potential bone marrow donors.

I want to accord at this point a good deal of credit to my colleague, Bill Young, from the House, and certainly Senators Gore and Mikulski who, in their former life as Members of the other body, really ramrodded this program.

I had, frankly, very little involvement with it at that time. Senator Gore was very nice in including me. But I really wasn't aware that it would matter a lot to me until it became of personal instead of professional interest. In August of 1987 my youngest daughter Anne, then 14 years old, was diagnosed with leukemia. And although we initiated a search through the national marrow donors program registry as well as other registries, no suitable match from an unrelated donor was found. Rather than wait for a donor which may never have materialized, we proceeded with a transplant between Anne and her mother. Although the match was less than perfect, we decided to go ahead with the procedure before Anne became too sick either from prolonged chemotherapy or the disease itself to be able to stand a transplant.

Fortunately, more than two years since her transplant, Anne enjoys good health and lives the active, normal life of a teenager.

I have maintained my interest in the program over the last few years and recently became more involved after learning of the plight of Amanda Chang, an infant from my congressional district in need of a bone marrow transplant, and a number of other people in my area of Sacramento, California, as well as the two local Washington area students that we have all heard about, Allison Atlas and Joanne Johnson.

The efforts of Allison's and Joanne's and other families in the area in initiating their own searches led me to look at the Nation's registry program, focusing on two areas. First, while I strongly support the National Marrow Donor Program and commend it on its success in facilitating more than 250 transplants, I have a concern that there are too few and not enough diverse donors in the registry.

I am also concerned that sufficient funds are not available to adequately test individuals willing to donate. Allison Atlas and Joanne Johnson's cases demonstrate the inadequate representation of certain ethnic and racial groups within the registry. This situation led me to draft legislation which I will be introducing shortly to provide a one-time $15 million authorization for the purposes of

testing potential donors, with an emphasis on populations inadequately represented in the registry.

This funding level will enable the registry to reach its goal of 250,000 registered donors. By building up the number of donors, fewer families will have to assume the burdens which the Atlas and Johnson families assumed.

Second, I am concerned about equal access to information about available options and the costs for those in search of unrelated donors. In many cases, families face major ordeals in their searches, using up valuable time and financial resources as they seek out that elusive life-saving donor. In some cases, it may even be best to follow the route which my daughter Anne took. The course a family takes may depend on initial doctor or hospital contact and may result in their coming up short of knowing all the available options. In some cases, unless families ask the right questions, they may never know what alternatives exist. As a result, I have asked the Office of Technology Assessment, OTA, to evaluate and report back on the NBMTP and other major registries to determine the success of the current system. I would like to submit a copy of the report for the record. It is entitled "Unrelated Bone Marrow Transplants in the United States: Policy Issues from a Patient Perspective."

The CHAIRMAN. Yes. It will be included in the record.

Mr. FAZIO. Thank you.

[The report of OTA follows:]

UNRELATED BONE MARROW TRANSPLANTS IN THE UNITED STATES:

Policy Issues from a Patient Perspective

Introduction

A patient who has decided to seek a bone marrow transplant for a fatal blood disease, and who has no siblings or other relatives who are sufficiently matched genetically, must find an unrelated matched donor for treatment to proceed. This Staff Paper discusses the paths patients may take to find such a donor, and some of the difficulties in the system as it exists today. The Paper centers on the policies and practices of the National Marrow Donor Program (NMDP), run under contract to the Federal Government, the American Bone Marrow Donor Registry (AR), a private donor registry, and the medical centers that perform unrelated bone marrow transplants.

OTA gathered information for this Staff Paper, which was requested by Congressman Vic Fazio (Chairman, Subcommittee on the Legislative Branch, House Committee on Appropriations), from NMDP literature, six NMDP-approved transplant centers, and from individuals at the NMDP, the AR, the Red Cross, the National Institutes of Health (NIH), and others.

The heart of the NMDP is a computerized data base of information on a current pool of about 80,000 individuals willing to donate bone marrow to patients in need of a transplant. Each potential donor is registered with one of the many local donor centers (mostly blood centers) around the country, on which the NMDP depends. NMDP also has relationships with certain transplant

centers (28 in the United States and 3 abroad, as of January 1990), which it approves, and which perform all transplants from donors identified through the NMDP.

Apart from the NMDP, there is one major private registry in the United States, the AR, with a total of about 28,500 potential U.S. bone marrow donors, and direct access to about four times that number in foreign registries. Three major foreign registries are not linked directly with either U.S. registry, but both the NMDP and AR may arrange for searches in those registries. There also are U.S. medical centers that perform bone marrow transplants from unrelated donors but are not currently approved by the NMDP. Major philosophical differences having to do with transplant center access, costs, search information, and approval of transplant centers divide the NMDP and AR.

From a patient's point of view, when a medical decision is made to attempt a bone marrow transplant, and when there is no available related matched donor, the only choice is an unrelated matched donor. Although the time scale varies somewhat according to patient and disease characteristics, there is always some window of time during which a transplant is possible, and after which the opportunity is lost.

The medical center at which the patient seeks a transplant determines, in large part, how the search for a donor will be conducted--whether many lines of search will be opened simultaneously or whether they will be opened sequentially, and whether certain registries will be missed altogether. The price of searching for a match and harvesting bone marrow also varies substantially by transplant center, even though the patient's transplant center itself is minimally involved in those activities and is paying the

registry (either the NMDP or the AR, whose charges for each component service differ) for those services. In some cases, the difference between a successful search and transplant and an unsuccessful one may lie in the variations of search and cost. The costs of searching for a donor and harvesting the donor's bone marrow are of particular concern, because search costs are rarely covered by insurance and harvesting is not always covered.

The National Marrow Donor Program (NMDP)

The major limit on the use of allogeneic (from any person other than oneself or an identical twin) bone marrow transplantation for patients who might benefit from one has been the lack of a matched relative and the historic difficulty of finding a matched unrelated donor. If unrelated bone marrow transplantation is to be a practical medical alternative, finding a matched donor must be feasible with something less than a heroic effort. Only with a large pool of ready potential donors, whose HLA types[1] are known and easily compared with those of recipients, is that possible. The NMDP was conceived by Congress to meet this need.

After three and a half years of operation, initially under contract to the U.S. Navy and the last year under the current contract with NIH, the NMDP has absorbed most of the preexisting private registries in the United States, and has recruited additional potential donors through permanent donor centers

1 "HLA antigens" are cell surface proteins that play a critical role in distinguishing "self" from "non-self." The different HLA loci (i.e., locations of the genes on the chromosome) are named A, B, C, and D (subdivided into regions DP, DQ, and DR). The three loci that are most important for a successful bone marrow transplant are A, B, and DR. Every individual has two genes for each antigen ("alleles") in their DNA, one from their mother and one from their father. So, a perfect match consists of six identical antigens. Transplants may also be performed with less than a six-antigen match; however, the poorer the match, the poorer are the chances for a successful transplant.

around the country and donor recruitment drives. About 80,000 potential donors are accessible through the NMDP computer system, all of whom have been HLA A,B typed, and about 33% of whom have been HLA DR typed. Registries in the Netherlands and Israel are part of the NMDP, discussions with Japan and several European countries have begun, and NMDP has established reciprocal search relationships with major registries in England, Canada, and France. As of January 1, 1990, 3,645 preliminary searches had been performed and 260 patients had received transplants from these searches.

The original target of the NMDP was to recruit 100,000 potential donors, but newer information on the distribution of HLA types has made it necessary to reset the goal in order to ensure a reasonable probability of finding a match for most patients. Regardless of the size of the registry, there will be patients with HLA types so rare that a match will not be found. There is a particular need to recruit enough ethnic minorities to assure matches for those populations, as well. NMDP is aiming to have 250,000 potential U.S. donors, and, with linkages to foreign registries, 1 million worldwide by 1995.

In addition to searching the registry for preliminary (on file HLA information) and final (adding HLA DR for potential donors who are not completely typed) matches for patients, the NMDP "approves" the transplant centers that they will allow to search the registry and perform transplants from NMDP donors. Unapproved centers may not initiate searches, and bone marrow from donors identified through the NMDP may not be transplanted in centers that are not approved. Approval criteria are drafted by the NMDP Standards Committee and then must be approved by the Board of Directors. The Standards Committee is composed of scientists and clinicians from participating and non-participating centers. Criteria for approval take into

account the experience of the transplant center physicians and medical facilities at the center (see Appendix for current approval criteria). NIH contends that approval of transplant centers is necessary to assure that donors do not undertake the risk of donation unless the potential benefit to the patient is maximized; in their view, this equates with having the transplant carried out in an NMDP-approved center. Currently, there are 28 approved transplant centers in the United States and 3 abroad.

Decisions about which donor registries to search and the sequence of searching them are up to the transplant centers. Some patients or their families become deeply involved in the search, but most leave the details to the transplant center physicians and administrative personnel responsible for those tasks. Transplant center policies on searching vary considerably. Some centers initially search only the NMDP, which does not include immediate searches of the large European or Canadian registries. If no match is found, they may go on to other registries not linked directly with NMDP. Most centers contacted by OTA searched the Anthony Nolan registry in Britain, the Canadian, and the Paris registries next; the NMDP will initiate these searches at the request of the transplant center, and will charge the center a fee for doing so, or the transplant centers may initiate the searches directly. For its searches, the AR immediately accesses the three major foreign registries and its own computer-linked national and foreign registries. Some transplant centers do not routinely search the AR at any time. Because the NMDP is not yet big enough to ensure a match most of the time, there is a reasonably high probability that no match will be found, and that for some patients, because of transplant center strategies, some registries will go unsearched, or

several months may pass before later registries are searched. In contrast, some NMDP-approved centers initiate searches simultaneously in the NMDP and the AR (which includes the three major unlinked foreign registries).

Transplant center policy on one other issue may be of major significance to a patient. This has to do with referrals to other transplant centers for transplants that the initial center will not undertake. The centers set their own criteria for the degree of HLA match they require for a transplant. Some require an exact 6-antigen match, but others will do a transplant with a single mismatch (some distinguish between major and minor mismatches). If a potential donor with one mismatch is identified, for instance, and the patient is at a center that requires a six-antigen match, the patient will not necessarily be informed that another approved center might do the transplant. The NMDP does suggest that transplant centers consider referring the patient to another approved center with different match criteria, search other registries for an acceptable match, or repeat the search periodically, as the NMDP grows. The centers are not bound to do any of these things, however.

Also of concern to patients is that the NMDP will not allow a transplant using a donor they identify to take place at any but an NMDP-approved center. In some cases, this has left a patient with a match acceptable to an unapproved center, but unable to secure the donor marrow. In other cases, having to go to an NMDP-approved transplant center might not be feasible for the patient or family. For example, OTA was informed of a child with aplastic anemia being treated at a university medical center in Texas, for whom a six-antigen match has been found in the database of an NMDP-approved transplant center. The family prefers to have the transplant performed at their hospital and does not wish to move the child to an NMDP-approved center. The center,

that has the match, whose donor center is affiliated with the NMDP, will not contact the potential donor for MLC testing until the child is enrolled in an NMDP-approved transplant center.

The American Bone Marrow Donor Registry

The other major option for finding a donor is the AR. The AR, run by a combination of paid staff and volunteers, is composed of several small registries that are independent of the NMDP. Most of these registries were begun in past years by families of patients unable to find a donor through then-existing registries. These files were maintained and expanded and today all branches are computer-linked with each other. The AR has 28,500 donors on file and direct access to more than 100,000 additional donors in foreign countries. Three major foreign registries, Anthony Nolan, Paris, and Canada, are not computer-linked to the AR, but the AR initiates searches in them at the same time the AR computer-linked registries are searched. Patients are also given forms to initiate searches in three additional foreign registries which require added fees -- one in Belgium, and two in Israel -- should they choose to do so.

A patient need not be affiliated with any particular transplant center to begin a search in the AR. The AR will provide search information directly to the attending hematologist or oncologist before the patient is referred to a transplant center. Eventually, if a match is found, the patient will choose a transplant center, but the AR does not designate particular centers that patients must use. The AR has conducted about 1,100 patient searches. Due to the policy of turning over patients to transplant centers and inadequate resources for follow-up, the AR does not have precise numbers of how many

transplants have resulted from their searches. The AR reports that twenty transplants have definitely taken place from donors in their database, and the AR may have facilitated as many as 110 additional transplants from donors in foreign registries.

Discussions that were underway concerning the development of a system whereby searches for unrelated donors could be routinely exchanged between the AR and the NMDP seem to have halted. Two registries that had been part of the AR, Heart of America and the New Jersey HLA registry, have joined the NMDP as members during the past year. The Heart of America no longer performs searches for the AR. The AR will continue, however, to have access to the New Jersey HLA registry.

Search Procedure Through the NMDP and AR

The goal of a search is to find an HLA-matched donor for a patient. In both registries, the procedure is similar, and in both the entire process takes a minimum of four months. The search is conducted in two parts: a preliminary search and a formal search. NMDP searches must be initiated through NMDP-approved transplant centers (attending physicians cannot activate searches in the NMDP), and AR searches may be initiated either by the attending physician or a transplant center. A few centers require an on-site evaluation of the patient before the initial search; however, most will begin the preliminary search after discussing the case with the patient's physician. The preliminary search generates, within a day, a list of donors with HLA A,B types and HLA A,B,DR types identical to the patient's or with one mismatch. Since a minority of potential donors in both registries are DR typed, most of the matches generated are only for the HLA A and B loci. There are many

different A,B alleles, each with different frequencies, so depending on the genetic makeup of the patient, there may be no A,B matches or as many as 200 (estimate from the NMDP). An "average" preliminary search turns up 10 to 15 A,B matches.

The formal search is a follow-up on these HLA A,B matches. Before a formal search is conducted through the NMDP, almost all transplant centers require an on-site evaluation of the prospective patient to ensure that he or she is still eligible for a transplant (i.e., that the patient's condition has not deteriorated so that a transplant is no longer possible). The AR will continue without a formal evaluation, based on the attending physician's determination. Potential donors with A,B matches are called to their local donor center to have blood drawn for DR typing (unless they are already DR typed). At that time, further information about the transplant procedure is given to the donor. DR typing usually takes between 3-4 weeks in the NMDP and 2-6 weeks in the AR. The few donors with DR matches must pass one final test, the mixed lymphocyte culture (MLC), to determine compatibility. This test involves mixing the lymphocytes of the donor and recipient; if they do not react, or react minimally, the donor is considered compatible.

If a compatible donor is found through the NMDP, the NMDP arranges to have the donor's marrow collected, which may be done at a large number of medical institutions (not necessarily transplant centers). Bone marrow can be transported, so it does not have to be harvested at the center where the transplant will be done. If necessary, transport to the patient's transplant center is arranged. After the transplant, the NMDP receives and maintains data on the success of the transplant. If a donor is found through the AR, the transplant center at which the patient is being treated arranges for

further testing and marrow procurement once a compatible donor has been identified. AR requires that the marrow harvest be done at a transplant center.

Patient Access to an Unrelated Bone Marrow Transplant

In beginning to seek an unrelated donor, the physician or family may call the "800" number of the NMDP for assistance; they will be referred to one of the 28 U.S. transplant centers with access to NMDP's registry. The NMDP "hotline" does not necessarily give information about any other registry. (The Executive Director of the NMDP told OTA that the hotline does discuss other registries, when asked. In inquiries made on behalf of OTA, the person who answered the hotline, when asked directly about the existence of other registries, gave no such information.) The physician also might refer the patient to a transplant unit with which he or she is familiar, which may or may not be approved by the NMDP, or might attempt to initiate searches through the AR or other private registries.

NMDP-approved transplant centers have their own guidelines for enrollment, and their own fees for NMDP services. Ten of the 28 centers will begin preliminary searches of the NMDP at the request of the patient; the rest require that the patient's physician contact the transplant center for enrollment. Except for the Seattle VA hospital, all NMDP-approved transplant centers also require demonstration of insurance coverage or an ability to pay before the formal search is initiated.

Costs for Donor Search and Bone Marrow Procurement

NMDP

The NMDP charges the transplant centers for its services. The initial search of the existing database is free. If no HLA A,B matches are found, no expense is incurred. If one or more HLA A,B matches are found, the "activation fee" for a formal search is $350. The charge by the NMDP to the transplant center for HLA DR typing (which involves drawing donor blood at the local donor center and having it typed at a contract laboratory) is $280 per sample. In general, all HLA A,B matched potential donors are DR typed. For potential donors who are acceptable HLA A,B, and DR matches, the NMDP will procure a blood sample for MLC testing for $98 per person (the actual MLC test is done at the patient's transplant center). There also is a $160 charge for infectious disease testing of the donor, which is performed by the transplant center. If a match is found, the NMDP charges the transplant center $12,900 for donor marrow harvesting, transport, and related costs (including life and disability insurance for the donor).

All of these charges are levied against the transplant center, which, in turn, charges the patient. Some transplant centers pass the charges on directly, with a small administrative fee. Others add on thousands of dollars in total. Transplant centers are free to decide how much they will charge; the NMDP does not dictate to approved centers how much they should charge for NMDP services. OTA surveyed four transplant centers for their charges to patients for NMDP services. Activation fees ranged from $350-$1100; DR typing from $280-$340; MLC from $98-$120; and bone marrow harvesting and procurement

from $12,900-$18,500. In addition to administrative costs, costs are incurred by some transplant centers for additional tests that they require; however, these costs are relatively small.

Treatment centers collect fees either directly from the patient or from his or her insurance company, but, based on information from transplant centers and others interviewed by OTA, most insurers do not cover search costs and a few will not cover procurement costs. Insurance coverage is generally available for the transplant itself, as long as bone marrow transplantation is not considered experimental for the particular indication.

If a match is found for a patient, search and procurement charges to the transplant center from the NMDP average $16,000-$20,000, but costs to the patient may be significantly higher, depending on the number of HLA DR typings and the add-on charges of the treatment center. The costs to the patient for an unsuccessful search average $4,000 (search activation, administrative fee, patient evaluation, 10 HLA DR typings, four MLC tests) but may go well above $15,000. Some transplant centers also charge patients a monthly fee to keep their searches active. Much larger costs may be incurred by the patient if a special donor registration drive is held (see "Recruitment of Potential Donors," below). If a family's money runs out, searches may be terminated.

If the Canadian, Anthony Nolan, or Paris registries are searched by the NMDP, additional costs are passed on to the patient, with or without an added transplant center fee. OTA has only approximate costs for these services. Search activation charges for the Canadian registry vary by user. The Anthony Nolan Registry activation fee is about $415, and the Paris Registry charges for DR typing only, with no activation fee. The HLA DR typing charges are

about $280, $165, and $234, respectively, for the three registries. At least one transplant center for which OTA has information charges patients above and beyond what they are charged by the foreign registries.

AR

The AR charges $300 to initiate a search for HLA A,B matches. There is no subsequent charge to move on to the formal search for HLA DR matches. The charge for HLA DR typing is $175 per person. After a DR match has been identified, the AR turns the patient over to the transplant center. AR usually charges the patient for donor insurance (medical, life, and disability). The marrow collection center and the transplant center charge the transplant recipient for marrow harvesting and transport costs and for additional donor services. The costs to an AR patient for harvesting and donor-related expenses average $5,000-$8,000 (corresponding to the $12,900 charge of the NMDP). AR search charges are billed directly to the patient or through the transplant center. AR requires that no administrative fee be added by the transplant centers to AR charges.

Recruitment of Potential Donors

There are two basic methods for recruiting potential bone marrow donors: 1) through permanent centers, logically blood centers of some sort (e.g., Red Cross), which would continually recruit donors; and 2) through drives for particular patients in which a large number of people in the community are recruited quickly in hopes of matching the person in immediate need, and then are added to the registry for the future. When the NMDP began under contract to the Navy in July 1986, the plan was to recruit apheresis (plasma and

platelet) donors through 55 affiliated donor centers. Apheresis donors regularly gave blood and were already HLA typed. Based on early experience and pilot studies, it was expected that 70 percent of them would agree to become bone marrow donors; the registry would then have a sizable donor pool without spending money on typing. The original budget did not include any money for typing, since it was believed unnecessary. Recruitment of apheresis donors fell short of the goal, however.

Donor centers are now in the position of wanting to recruit interested, stable donors but having no money for typing. Donor centers must cover the $75 HLA A,B typing fee for each non-apheresis donor added to the national registry. (DR typing is a more technically-demanding and expensive procedure, done only at specialized labs.) Most of the smaller centers are not recruiting donors, since they are unable to cover the costs. Many centers urge people interested in entering the NMDP to become an apheresis donor, or will ask them to cover the costs of their own typing ("your marrow and your money"), which has been the cause of some ill feeling on the part of potential donors. Some donor centers have solicited business contributions, received grants from private organizations, and sponsored runs and other events to raise money to cover the costs of typing. The NMDP gives the donor centers $5 per newly recruited donor, and about $12 per year per donor for database maintenance and follow-up.

Typifying the second recruitment method, Life-Savers, one of the official donor-recruitment affiliates of the NMDP, comes into communities and holds recruitment drives for specific patients whose registry searches have failed. Volunteers with the same ethnic background as the patient are targeted, with the hope of finding a match. Even using this strategy, chances

of finding a match are quite slim in most cases. Potential donors recruited this way are also asked to become part of the national registry for future searches. In addition to patient-specific drives, Life-Savers also organizes group-sponsored drives (e.g., Lions Club, Optimists, colleges, churches, etc.) and sponsors ongoing individual testing.

In patient-specific community drives, patients and their families are responsible for covering the $75 per person cost of HLA A,B typing for each potential donor. However, if families are unable to pay, the Life-Savers will assist in raising contributions to cover typing costs. Nonetheless, the family may bear as much of a financial burden as it can. The major beneficiary of these drives is the NMDP itself, in expanding the pool for future searches.

Regardless of how a donor is recruited, he or she must be associated with a permanent donor center, the mechanism by which people are followed up and contacted in the event of a match. Life-Savers gives potential donors' names and HLA A,B typing information to local donor centers wherever they conduct their campaigns. (Life-Savers contracts with laboratories for HLA A,B typing.) Under the current one year contract from the American Red Cross, LSF receives $500,000 to cover administrative costs.

Community recruitment drives raise some potential problems. According the NHLBI, potential donors may be recruited who do not meet NMDP criteria (e.g., for age, disease history) because screening is faulty. In addition, testing laboratories may be overwhelmed by large numbers of samples that must be processed in short periods of time. Local donor centers may be faced with hundreds or thousands of potential donors to enter into their computers, and a

long lag may occur before they are all in. There is also a danger that patient-specific drives may attract donors willing to donate for that patient, but not for an unknown future recipient.

From the information OTA has gathered, it appears that the need for patient-specific drives is, at least in part, a consequence of the lack of funding for typing in the NMDP budget. The result is that the financial burden for expanding the registry is placed on the private sector, and specifically, on patients and their families.

The lack of DR typing for most potential donors, again related to the fact that the NMDP budget has no money for typing, also affects patients' chances of getting a transplant. The search procedure is slowed considerably as patients wait for DR typing to be performed on A,B matches. Not only must patients pay a premium for "rush" DR typing, but the 3-4 week waiting period may close the window of opportunity for a transplant. Transplant centers can only effectively serve patients with chronic disorders, and not potentially-eligible patients with acute leukemias.

NMDP Organization and Future

Dr. Jeffrey McCullough, NMDP Principal Investigator, commented that "it is the end of the beginning" of the NMDP. The program has built a framework connecting transplant centers and donor centers to a coordinating center, has amassed a large registry in a few years, can perform searches rapidly, and has facilitated more than 250 transplants. A powerful Board of Directors is in place that oversees NMDP operations, and several committees set policy guidelines and provide a general direction for operations. However, there are a number of conflicts and issues concerning the current operation and future

plans of the program that need to be resolved. To some extent, all of these may affect patients looking for unrelated bone marrow donors. It is not the purpose of this Staff Paper to delve deeply into the management of the NMDP, so the issues will only be mentioned briefly.

Perhaps the largest conflict concerns the management of the NHLBI contract. The program has been a collaborative effort of the American Red Cross, American Association of Blood Banks and the Council of Community Blood Centers, with the Red Cross designated the administrative recipient. The Board of Directors of the NMDP voted in June 1989 to apply directly for the contract and remove the administrative layer of the Red Cross. The Red Cross would still wish to play a major, but yet to be determined, role even if it were not the primary NMDP contractor, believing that the long-term donor recruitment and maintenance goals of the program are best served by maintaining strong ties to blood centers. Red Cross does not believe that the need for independence has been demonstrated, but accepts the desire on the part of the NMDP for change.

According to the NMDP Executive Director and the NHLBI, the NMDP Board deals more or less directly with NHLBI, and in effect does not report to the Red Cross. Red Cross has encouraged independent operation of the NMDP, but retains controls to meet its obligations to NHLBI as contractor of record. NHLBI accepts independence for the program, and describes the original affiliation with the Red Cross as largely one of convenience, a means to get the program organized and operating rapidly without having to create an entirely new administrative structure. Red Cross does not, however, and never

has, viewed its role as one of convenience. The current contract with the Red Cross expires on April 30, 1990. NHLBI is planning to extend the contract for another year before renegotiating the terms.

According to the Institute Director, NHLBI has considered alternatives to the current management and organization of the NMDP. The central variable is how closely NIH will eventually manage the program. Under the current arrangement, the Board of the NMDP, while consulting with NIH, largely determines virtually all operating policies. Presumably, key management decisions will be made by NIH before the current contract (as extended) runs out.

Summary: The Patient Perspective

The NMDP has made great progress in its three years of existence, but it does not entirely meet the needs of patients and their families in facilitating the search for an unrelated bone marrow donor. NMDP is organized to provide services to transplant centers and to conduct research on unrelated bone marrow transplants. (OTA did not examine the extent to which the research objective is being met. Given the increased demand for unrelated transplants, it would seem imperative that research be carried out to find out in which patients this technique is likely to be beneficial. When OTA examined this issue in 1987, relatively few appropriately controlled studies were going on.) Patients have no direct relationship with the NMDP, and NMDP does not claim to be a patient advocate of any kind. The public, however, may be expecting that it does fill that role, so a problem in perception may exist. The AR, by contrast, is clearly in the patient advocacy role; they consider their clients to be the patients rather than the transplant centers.

The major search decisions are left to NMDP-approved transplant centers, which have a variety of policies for searching, for carrying out transplants, and for informing patients of other options, should their transplant criteria not be met. Patients may not necessarily be aware of exactly what decisions are being made, and what options chosen or rejected on their behalf.

From the patient's perspective, the relatively large difference in the cost of finding a donor through the NMDP and the AR may be significant. In addition to AR's concern that their philosophy of patient advocate does not exist in the NMDP, they are concerned by the larger financial burden placed on families by NMDP-acquired transplants. It is difficult to compare the costs incurred through the NMDP directly with those of the AR, since somewhat different services are provided, and the administrative structures of the registries are quite different. However, it is clear that the difference to patients can be thousands of dollars, much of which is paid out-of-pocket.

It would clearly benefit patients and transplant centers if the largest possible pool of donors could be searched quickly and efficiently. In the longer term, this may become the case if the NMDP reaches or exceeds its target figure of donors. For the present, however, it does not appear that this will be possible until some of the philosophical and financial differences between the NMDP and the AR are examined and resolved.

Appendix 1

CRITERIA FOR PARTICIPATING TRANSPLANT CENTERS

1. Centers must have performed at least 10 allogeneic transplants per year during the previous 24 months and at least 30 in the previous five years;

2. The center director must have had two years experience in an NMDP-accredited transplant center or in a center recognized by publication in peer reviewed journals to be capable and experienced;

3. A dedicated transplant team must have been in place for a minimum of two years and there must be a designated nursing unit for marrow tranpslantion;

4. Data must be submitted on the results of all allogeneic transplants done in the previous five years. The NMDP Membership Committee will evaluate the results and then determine if the center's overall record justifies membership. A site visit may occur as well;

5. Medical support services must be adequate; and

6. The center's protocols for unrelated donor transplants must have been approved by a local Institutional Review Board.

Mr. FAZIO. Since the report is available, I will not elaborate on it except to say that the goal of a centralized, coordinated system to facilitate bone marrow transplants has really not yet been fully realized. After experiencing the process myself, I strongly believe there needs to be a system whereby individuals and families can receive thorough responses to their questions about available options. We need to insure that the program is as effective as possible, at least, in matching unrelated donors with those in need and that the process exacts as small a financial and psychological toll as possible from those utilizing the program.

I think we are on the verge of perfecting the system. What we do need, as Senator Gore has indicated, not only support from the Administration but financial support from the Congress.

Congressman Young and I have conversed with Chairman Natcher on our side and we are very hopeful that this year, even perhaps without the authorization that we all seek, there will be some additional infusion of funds. And certainly your hearing here today, Senator Kennedy, and the support that you and others have given on this side of the Capitol gives us great hope for the breakthrough that I think we can make during this session of Congress.

Thank you very much.

The CHAIRMAN. Thank you very much.

Congressman Young.

Mr. YOUNG. Mr. Chairman, thank you very much to you and the members of the committee for having this hearing this morning.

We are talking about a dramatic, life-saving procedure here that should not overlooked and where our interests should be emphasized at every opportunity. And I think that this hearing today helps do that.

About 20 years ago, a doctor named Robert Goode developed the process of transplanting bone marrow from a healthy patient to a patient in need of that transplant. It was experimental, but it worked. Dr. Robert Goode is a physician now and a researcher at All Children's Hospital in St. Petersburg, Florida, and I have known him well through the years.

But since that 20-years-ago procedure was developed, we have come a long way. It was just five years ago that we didn't have any participation on the part of the Federal Government in establishing a registry or seeking out donors to give the gift of life to terminally ill patients with leukemia and other types of blood disease.

Since 1986, though, the Congress has, as has been pointed out on several occasions here. The Congress began with the United States Navy, with a $3.5 million appropriation to get the national registry started. The results were dramatic: nearly a 70 percent success rate in those fatally ill patients who were able to receive a nonrelated transplant through this registry. And in that four short years now, we are having again a tremendous success.

But in addition to the names that you have mentioned, Mr. Chairman, and that Senator Gore has mentioned and Congressman Fazio has mentioned, there are some 9,000 other Americans waiting today for that gift of life from someone whom they don't even know exists, someone who might be a matched but unrelated bone marrow donor.

Mr. Chairman, I have taken on the project of trying to find the donor for every one of those people that need a match. In my district there is Grant Hartley, 26-year-old black man, Jolene Faggion, a 7-year-old girl, Amanda Early, a 3-year-old girl—all in need of a transplant. And every day their need grows greater because their physical condition gets less.

In the last couple of weeks, Mr. Chairman, we started a pilot project that has worked extremely well. We sent a mailing into the district, the Eighth Congressional District of Florida. We made personal contacts with business leaders and industry leaders. And the result is tremendous. In this mailing we sent—and I brought a copy of it for the committee to see, and incidentally I have sent a copy of this whole package to all the Members of the House and the Senate—we tell people about the program and we ask them to respond with a coupon if they are interested. And the results have been overwhelming by people who want to be considered to give the gift of life through a bone marrow transplantation.

In addition, because there is a $75 charge for the typing, and frankly the Congress has not appropriated enough, as Mr. Fazio has mentioned, to bring that registry up to 250,000 people, we have found that industry after industry in the Eighth Congressional District of Florida have agreed to not only support the program with their employees but also to defer the cost, to pay the $75 per person typing fee. The result is really tremendous.

We put this package together, and we have passed it on to our colleagues in the House, and we are sending it to our colleagues in the Senate, suggesting maybe they would like to do the same thing in their own districts.

I believe that if we can do this, we can not only find the financial help from industry in addition to the money that we intend to appropriate this year for the national registries, I think we are going to find a very successful program of expanding the donor registry much quicker than any of us had anticipated.

Mr. Chairman, every day you learn a little more about this. Every day the issues become more clear. Today we need donors. We need to expand this registry. We need to appropriate the additional money that Mr. Fazio is talking about so that the naval laboratory and the National Institutes of Health laboratory and the other agencies who are under contract can type the thousands of people who are now prepared to have their marrow typed.

As I say, Mr. Chairman, it is a simple procedure. I have been typed, and I am in the registry. All of my staff have been typed. My wife has been typed. And it is a simple blood test, 30 cc's of blood that are sent then to a laboratory to be typed for the antigens that are necessary to be typed to be the critical match. Hopefully, other Members of Congress will be willing to sponsor a program of this type. The result has been tremendous.

I am meeting with the Black Caucus later on this week because there is a serious problem, as has already been mentioned. The black terminally ill patient, the Hispanic terminally ill patient, the various genetic groups, the various racial groups who need help will more than likely find them in their own type of a genetic environment. So it is important that we reach out not only to white America but to all of America to have their marrow typed, be will-

ing to be a donor, be willing to give the gift of life to that person who is not going to survive unless they have this gift.

In St. Petersburg, Florida, there is a young man named David Smith. David is 25 years old. He was a bone marrow donor. He has saved the life of a fellow American. And I asked David the other day how did it feel. I have been asked that many times does it hurt. He said, well, he was sore for about three days, but on the third day he was back out jogging again. So the procedure is not that big a deal. It can be done in a very healthy environment. And I am hopeful that we are going to provide the money for the Federal Government to be a player. I am hopeful that other Members will approach their business and industry communities and their constituents and let's find donors for these terminally ill patients with leukemia and other types of blood diseases.

Incidentally, Dr. Goode tells me that we now have gotten to the point there are some 60 blood diseases that the bone marrow transplantation is a treatment for and a cure for.

Mr. Chairman, thank you very much.

[The prepared statement of Mr. Young follows:]

PREPARED STATEMENT OF CONGRESSMAN YOUNG

Congressman YOUNG. Mr. Chairman, thank you for giving me the opportunity to share with you today my thoughts on the future direction of the National Marrow Donor Program.

One of the most rewarding experiences of my whole life has been leading the effort in congress to establish this national registry—a program that is saving lives every day by bringing together a patient in need of a transplant with a matched donor. As you know, bone marrow transplantation is a preferred treatment for leukemia and as many as 60 other blood disorders. When successful, it is a cure. The procedure, however, requires very precise tissue, or "HLA," matching of the donor and recipient. In fact, the typing is so critical that the chances of finding a matched donor are about one in 20,000 and that is why it is so important that we mount a nationwide effort to expand the registry.

Prior to the establishment of the national registry, doctors treating patients in need of a transplant had to make hundreds of calls to individual blood banks and hospitals in search of a potential donor. In most cases, the search was futile or took so long that the patient, with the fatal illness, was no longer strong enough to undergo a transplant.

In 1986, the Congress appropriated the first funds for the Navy to begin the process of establishing a computerized registry of volunteers who were willing to have their bone marrow typed and their names placed on call. As a member of the Defense Appropriations Committee, I worked closely with the Navy to ensure that they had the funding necessary to initiate this project. Oversight of the program last year was transferred by the Appropriations Subcommittee on Health, on which I also serve, to the National Institutes of Health.

Through the goodwill of more than 90,000 individuals who have already volunteered to have their marrow typed, we have established the National Marrow Donor Program. Now, with one request, a doctor can start a computer search and in a matter of hours determine whether there is a matched donor available. Where before there was little chance of survival for these terminally ill patients, there is now hope. The first transplant utilizing the registry took place in December 1987. Since then, there have been more than 300 transplants. Currently, 25–30 transplants are performed in the United States each month. This is only the beginning for this program which could soon help provide life for as many as 9,000 Americans a year, or 25 per day.

Four years ago, a national bone marrow donor registry was only a dream. A little over 2 years ago it became reality. This is a tremendous, working program that is saving lives. Its potential is limited only by the success rate of matching patients and donors. This is where our challenge lies in the months ahead. To improve the odds of finding an unrelated donor through the registry, we need to recruit and type

more volunteers. Our goal is to expand the list to 100,000 later this year, to 250,000 soon thereafter, and to 1 million volunteers world-wide.

Our experience with this project has shown that when Americans learn of the registry and the potential for saving lives, they readily volunteer to have their marrow typed and their names placed in the registry. The two greatest limitations on our recruitment effort is getting word throughout the country that we are seeking volunteers, and finding the facilities and resources to type them. We are doing all we can to spread the word about the registry and to provide funds to pay the $75 fee for the sophisticated lab test required to type each volunteer.

We also need to diversify the donor pool to ensure that all races and minority groups are well represented. Research has shown that because the tissue typing of a donor and patient must be so exacting that genetics plays a major role in a successful transplant. This research also shows that good matches most often occur when a donor and recipient have the same racial background. For example, blood donors best match black patients. The same holds true for Hispanic, Jewish, Eastern European, Asia, or Indian matches.

There is a four-pronged approach I believe we must take to recruit and type volunteers for a large and ethnically diverse national registry. First, as a member of the House Appropriations Committee, I will make every effort possible to include funding in the fiscal year 1990 Supplemental Appropriations Bill to provide the National Marrow Donor Program, through the National Institutes of Health, with resources to type the thousands of volunteers nationwide who have expressed an interest and are on waiting lists to join the registry, but who cannot afford the lab fees, and to do a better job recruiting minority donors.

Second, through my work on the Health Appropriations Committee, I plan to provide additional funding in the fiscal year 1991 appropriation for the National Institutes of Health for the continued administration of the program, to expand efforts to recruit and type volunteers, for dedicated research utilizing the registry, and to further ongoing efforts to link our national registries with similar registries throughout the world.

Third, through my work on the Defense Appropriations Committee, I have already begun efforts to initiate a program within the Department of Defense to recruit uniformed and civilian members of our Armed Forces and their spouses who would like to volunteer to be a part of this program. The Navy is at the forefront of bone marrow transplantation research and maintains one of the finest typing facilities in the world. With funds to be included in the 1991 Defense Appropriations Bill, the Navy will not only be able to type military personnel but also to develop more accurate and less costly HLA typing techniques.

Finally, the fourth component is a nationwide effort to encourage donor recruitment drives in communities throughout our Nation. Earlier this month, I launched a pilot program in the eighth Congressional District of Florida I represent to recruit volunteers for the registry and to encourage businesses to become involved in the program by covering or defraying the cost of the lab fees for their employees who volunteer. The reaction to our project has been unbelievable as thousands have volunteered to be typed and a number of major employers have agreed to cover the cost of the tests for their employees. Our local newspaper, The St. Petersburg Times, has strongly endorsed our project as has President Bush and Secretary of health and Human Services Dr. Louis Sullivan.

In addition, to show support in Congress for this national effort, I am making arrangements to type all interested Members of the House and Senate so they can be included in the national registry. The only requirement to be a volunteer donor is that you be in good health and between the age of 18 and 61. Prior to last week, the age cutoff was 55. However, during a meeting of the Board of Directors of the National Marrow Donor Program in my district March 9, the board, at my request, raised the maximum donor age from 55 to 61.

Mr. Chairman, the success of this program has been remarkable and is directly attributable to many dedicated volunteers such as Dr. Bob Graves and Admiral Bud Zumwalt who gave of their own time and energy to get this project underway. The registry, however, revolves around the notion of people giving of themselves to help another in need.

We are at the threshold of an exciting new era when thousands of people with once terminal medical conditions will be given the opportunity to live out long and productive lives. As we kicked off our local effort to recruit donors in St. Petersburg, FL, I had the opportunity to meet a number of local children and adults who are in need of a transplant but have yet to find a donor. There was little 7-year-old Jolene Faggion, 3-year-old Amanda Early, and 26-year-old Grant Hartley.

Mr. Chairman, there are not only men, women, and children in need of donors in my district, but throughout our Nation. There is Anissa Ayala in Walnut, CA, Harry Sydlow in Denver, CO, Kirsten Doney in Springville, UT, Ethelyn Hayes, in Mobile AL, Rick Quam, in Green Bay, WI, Kent Kiekow, in Mundelein, IL, Bob Farber, in Cincinnati, OH, Scott Wavra, in Northfield, VT, Donna Ravin, in Watertown, CT, Ben Takatsch, in Newark, NJ, and Allison Atlas, right here in Bethesda, MD, and hundreds of others throughout the country.

As we kicked off our pilot recruitment drive, I made a promise to Jolene, Amanda, and Grant. It is the same promise that I make all those in need of a transplant—that we will do everything we can to find compatible donors so that they will have the opportunity to experience all that life has to offer—to become teenagers, to raise their own children, to become grandparents, and to be the most gracious of great grandparents.

This member intends to keep that promise by pursuing every avenue of support for the National Marrow Donor Program. Mr. Chairman, I appreciate your support for our efforts and I look forward to working with you and the members of your committee in the weeks and months ahead to provide the living gift of life for thousands of Americans.

The CHAIRMAN. Thank you very much.

This has been an excellent panel. We hear Members of Congress speak on a lot of different issues, but I think this morning we have heard three speak about a public policy concern, a health concern, a family concern in our society, with great conviction and commitment, and we want just to thank all of you for being willing to share this with us.

I have no questions of this panel. I will recognize Senator Kassebaum and then our other members.

Senator KASSEBAUM. Thank you, Mr. Chairman. I thought it was very interesting testimony from all three, all of whom have been very involved in getting this off the ground. I think we all share a deep interest and concern in the program.

I would just ask one question regarding something that has been a concern as this has evolved, and that is the coordination of the system.

I think, Congressman Fazio, you touched on that, the centralization of a coordinated system, and I wondered if you had any recommendations of ways that better coordination could be accomplished?

Mr. FAZIO. Well, I think this is an issue that has to be looked into. We had a certain maturation of the program. We still have registries that are not completely cooperative, as I see it. I think the families of the victims really need to have one-stop shopping, so to speak. I realize this is a difficult issue for some of the people who have been pursuing their own strategies, and I think everyone is well motivated but there are a variety of approaches.

I think the families are confronted, very often, with perhaps one point of view when they go to find out whether there is an unrelated donor. It may depend on the center, the medical center they're dealing with, the particular point of view of their doctor.

I think we need to take some of the confusion and mystery out of the situation that confronts the patient and their family. I don't have the solution to offer you, but I think we can work toward it. I think there has to be a view of the patient's needs kept primary in mind, and some of the other issues that, I hate to say it, but border on turf issues, need to be reviewed thoroughly. And if we can find a way to get the kind of complete access to registries that I am not

convinced every child gets, I think we will have made a real breakthrough.

Senator GORE. Mr. Chairman, if I could comment in response to the same question. First, for the record, even though she did not note it, it should be in the record that Senator Kassebaum is a member of the National Marrow Donor Program board and has been actively participating in a leadership role.

The two registries should be combined. Both of them do great work. The individuals running them are fantastic. But the overall needs of the American people can best be met if in the reauthorization you can find an imaginative way to put some pressure on them to come together. They are both great, but they can be better than the sum of the parts, and I would urge that.

Senator KASSEBAUM. Thank you very much.

Would you agree with that?

Mr. YOUNG. Senator, I would agree with that, and I think you will have some expert witnesses on your third panel this morning who are involved with different aspects of all of the registries through the coordination of the National Institutes of Health. You will hear from Dr. Lenfant later this morning.

But I believe, as Senator Gore and Mr. Fazio have said, that we need to make it as simple as possible to find the donor without delay because delay costs lives.

Senator KASSEBAUM. Thank you very much.

Mr. YOUNG. Dr. Lenfant has about worked it out. He has gotten real close to it, but we need a little extra push to get him over the hurdle.

The CHAIRMAN. Yes.

Senator KASSEBAUM. Thank you.

The CHAIRMAN. We will give him an opportunity here in just a little bit.

Senator Metzenbaum.

Senator METZENBAUM. Well, Mr. Chairman, I have just one question, but I came over especially to commend you and the other Members of Congress who have provided leadership in this area. There are so many issues that we face in the field of health and so often there is no answer, we don't know what to do about it. This happens to be an area in which something can be done about it and is being done.

I want you to be assured that if in any way I can be helpful with my support, I am committed to doing so. I can't think of anything more important. Here is an instance in which you can actually save lives without some unbelievably Herculean kind of approach. It can be done, it is being done, and it ought to be expanded upon, I commend Congressman Fazio's move in that direction to add a rather modest amount of money to help do it.

I do have one question, and that is, would it be feasible when somebody donates blood, to inquire of them as to whether they would want to be registered in the bone marrow program at the time of the donation, on a voluntary basis?

And second, would it be feasible, when somebody applies for a drivers' license, to inquire of them as to whether or not they would be willing to donate their organs or whether or not to be registered

in the bone marrow program and then be contacted at a subsequent point? Does that make any sense at all?

Mr. FAZIO. Well, let me just comment. The California drivers license program is perhaps something you should look at. It provides for the opportunity for people to provide organ donations. I don't know that they are currently dealing with bone marrow as effectively as they have other organ donations. But Senator Gore, being an expert in this area, may want to comment further.

But I think it is a model that other States could look at. I know some are.

I do think, however, that the question of using people who are donating blood as potential marrow donors is a good one. I would certainly like to hear from Dr. Graves and others who have probably explored these options. I think it is a potential source of an awful lot of new volunteers.

Senator GORE. If I could comment on this.I think it does make good sense to approach blood donors about bone marrow donation, and putting donor cards on the back of drivers licenses has been an extremely helpful public education tool, but the committee needs to look at the real bottleneck here, which is the cost of the tissue typing. We need an extra $4 million to do the tissue typing on those extra donors we are trying to recruit now. If we suddenly had millions of new donors from the blood donation program, you would be faced with a much larger expense of tissue typing all of those or else just leaving the blood sample somewhere until you could get to them. That is really the bottleneck. It is about $100 per tissue typing.

Second, private insurers do not cover the cost for the donor, even though it's a small cost. And they should. And so I would urge the committee to also look at that bottleneck.

Senator METZENBAUM. If there were greater volume, could we bring the cost of the tissue typing down?

Senator GORE. Absolutely.

Mr. YOUNG. Senator, there is reason to believe that the cost can be brought down. Different experiments are being done now, research in finding better ways to do the typing.

The truth of the matter is, though, that we really ought to be appropriating more than the $14 million because the $14 million takes care of typing four of the six antigens, and then if the four match up with four of the patient, then you have go to back and type all of those again who have the first four.

We would really be smarter, I think, in the long run to do the six antigen typings all at one time. That makes it a little more expensive per typing, but it saves the added expense later on, and it could save months in the process.

So I think that is important.

To your specific question, the St. Petersburg Community Blood Bank has 286 blood donors today who have asked that their blood be typed, that their tissue be typed for the HLA typing, but the money at this point hasn't been there. That's why we have developed the program there of getting industries to help defray the cost.

We even had one private individual who gave us $100 million worth of computer equipment because he wanted to be part of this

great effort. And while the unrelated bone marrow transplant is relatively new, only about four years old, and the first one done through the registry was in December of 1987, it has really caught on, and the media has done a very good job in helping spread the story of bone marrow transplantation.

Your ideas, I think, are excellent, and Florida also does have an organ transplant arrangement when getting your drivers license.

Senator METZENBAUM. Thank you.

Thank you, Mr. Chairman.

The CHAIRMAN. Senator Mikulski.

Senator MIKULSKI. Senator Kennedy, I just wanted to comment along with my colleagues, who, as Congressman Fazio said, I work with in the House on this. These three Members of the Congress have taken both an individual interest as well as an individual strategy and turned their efforts into a public policy effort that has been really sustained over a significant amount of time. Senator Gore and I were in the Energy and Commerce Committee, where when he advocated his Organ Transplant Act, I was the one that established the first Federal bone marrow registry in 1986.

I just wanted to share with the committee some insights. First, this problem came to my attention not from a think-tank, not from public policy advocates, but it came to me because of a determined dad, a determined dad in Baltimore who called me to talk about his concern. And I find that most of the energy, most of the momentum, most of the ideas, most of the effort, most of the activity, and most of the advocacy comes not from people involved in traditional health and policymaking, but come from highly determined dads and highly motivated moms. It is the moms and dads that have made the marrow registry work to the extent that it has.

That was number one. And I think we might have to light a little fire under the traditional structures that we have here to move this legislation. That was number one.

Number two, what we also found, even from 1986 and it continues now, the continued turf warfare over who does the registry and who keeps track. Everybody wants to be "the" national center. What we are talking about, and I believe our colleagues have advocated, is there is room for everybody. There is so much work to be done, so much testing, so much research, so much matching up. It doesn't matter who is "the" national registry. In fact, perhaps we shouldn't have one, we should have "the" national network linking up all of these individual ones.

I would hope that again through our concerns here we would begin to put aside the turf warfare that has gone on.

Last but not at all least, this is an evolving science. It is not a fixed science. We know more today than we knew before because of the fine scientists in the field and the experiences that have come.

What we now know is the lack of certain minority constituents represented. The need to recruit volunteers has been, in some ways, the least of our concerns. The fact that we need to pay for testing is something that we did not anticipate, that is, the extent that it would be needed when we first created the program.

So, Mr. Chairman, this has been a long road, and I would like to thank my colleagues for their efforts and also those determined dads and the motivated moms which I know we will be meeting. I

would hope we would look at not only funding but the ending of the turf warfare and know that every day we are going to learn something new and every day we will learn something that will help us make it better.

The CHAIRMAN. Thank you very much. We will look forward to working with you as we reauthorize the legislation. We appreciate it.

Our next panel is composed of citizens who are currently involved in searches for suitable unrelated bone marrow donors, and I deeply appreciate their willingness to share their personal experiences with us.

We are pleased to welcome Ms. Sandy Mortensen; the Green family from Fairfax, VA, Ms. Kathy Barrett; and Mr. Alvin Atlas and his family from Bethesda, MD.

We will lead off with Ms. Mortensen. And Ms. Mortensen has organized the Help Jocelyn Fund in an effort to find a suitable donor for the daughter of a friend, 5-year-old Jocelyn Green. Jocelyn is here with her mother Suzanne.

Jocelyn, I am glad you have a chance to be here today.

Ms. MORTENSEN. Senator, Jocelyn wants to give you something.

The CHAIRMAN. You have something for me, Jocelyn? You come over here. You can come right over here now and say hello. We had a little chat before about foxes and bunnie rabbits, which we like best.

Have you been out here drawing this picture? Are you going to tell me about it? Look at this. Look how big this person is. [Laughter.]

Senator MIKULSKI. And how slim. [Laughter.]

The CHAIRMAN. This is a big person here, but he's got a smile on. Doesn't he have a smile? And she's got a smile; Jocelyn has got a smile too. Have you got a smile for me? That is so nice.

Well, if you would like to, Jocelyn, you can either stay in the hearing or you can go outside and color a little more. I want to see that fox and the bunnie rabbit you told me about, before you leave here this morning.

OK. Thank you. Do you want me to draw you a picture? [Laughter.]

We'll see.

Well, as I mentioned, I will ask Senator Mikulski to introduce some very special people from her own State in just a moment. Just in a general sense, I want to tell you how much we appreciate your sharing these experiences with us. As someone who has had some anxiety in my own life, talking about children and their challenges, in this case cancer, we know it's awfully difficult to talk about our own personal tragedies, and I think that that is an inherent kind of a sense that all of us have in terms of personal privacy. But I think all of you have faced that kind of personal anxiety, and because you have, Lord knows you have saved a lot of lives and made a very important contribution to increase the awareness of many of our fellow citizens about this challenge as well as the opportunity. So we will move ahead and we will start off with Ms. Mortensen.

STATEMENTS OF SANDY MORTENSEN, FAIRFAX, VA, ACCOMPANIED BY JOCELYN GREEN; ALVIN S. ATLAS, BETHESDA, MD; AND KATHY BARRETT, WOODBRIDGE, VA

Ms. MORTENSEN. Good morning, Mr. Chairman, other members of the Labor and Human Resources Committee. My name is Sandy Mortensen. I am a volunteer to assist the Greens in finding a bone marrow transplant donor for their five-year-old daughter, Jocelyn Dawn Green. Jocelyn was adopted by the Greens August 16, 1985, through the Prince George's County Department of Social Services, Prince George's County, Maryland. The Greens's only other child, Jason, two years old, was also adopted through Prince George's County Department of Social Services. They are not biological brother and sister.

Mr. Green wanted to appear and speak to you himself, but due to the sensitive nature of his job with the United States Department of Justice, he is not allowed to do so. Mr. Green requested that I relate the following to you:

On January 24, 1990, Jocelyn was taken to her pediatrician because she had symptoms of a cold. While there, Jocelyn was given a routine physical examination. Her doctor discovered her spleen and liver were enlarged. As a precaution, he ordered a blood test. Later that day, the doctor advised the Greens Jocelyn had a high white blood cell count. He stated he wanted her admitted to Georgetown University Hospital immediately.

Further examination at Georgetown disclosed that Jocelyn has chronic myelogenous leukemia, or CML. The doctors at Georgetown advised us that this disease can be treated for up to three years with chemotherapy, but her only chance of survival is a bone marrow transplant. Jocelyn's best chance of surviving the transplant is within this year.

On January 30, 1990, the Greens met with representatives of the bone marrow transplant unit of the Vince Lombardi Cancer and Research Center at Georgetown University Hospital. The Greens asked what would have to be done to set up testing sites to find a donor for Jocelyn. They were referred to an organization named Lifesavers. They were also told that the largest bone marrow donor registry was located in London, England. It was further advised that the National Bone Marrow Registry was maintained by the National Institutes of Health. At that time they were not advised of the American Bone Marrow Registry or any others.

I personally contacted the Lifesavers organizations on three separate occasions, at three different telephone numbers, for the Greens. I informed them that I was trying to set up testing sites for Jocelyn, who has CML. Each time, I was told someone from the Lifesavers organization would contact me. I am still waiting for that call.

The numbers I called are 800-999-8822, 818-967-8425, and 818-967-1500. I complained to the National Institutes of Health regarding the lack of response. An individual at NIH advised me that Lifesavers would be contacted for us. Again, we have received no response to date.

Joanne Johnson, another leukemia victim, who died recently, was a patient at Georgetown University Hospital. During the

period of time that Jocelyn was an inpatient, Howard Johnson, her father, was aware of the Green's wanting to start their own search for their daughter. Mr. Johnson stated he too had been steered to the Lifesavers organization. He talked of having a horrible experience with Lifesavers. He recommended contacting Joan Keller, president of the American Bone Marrow Donor Registry in Mandeville, Louisiana. He stated that Lifesavers required a large down payment prior to assisting in setting up testing sites. He added that the American Bone Marrow Donor Registry did not require a down payment.

He further advised us that Lifesavers charged $75 per test, and the American Bone Marrow Donor Registry charged $60 per test. Based upon Mr. Johnson's recommendations, I contacted the American Bone Marrow Donor Registry for the Greens. No one at Georgetown University Hospital, the Vince Lombardi Cancer and Research Center or the National Institutes of Health ever mentioned the American Bone Marrow Donor Registry to the Greens or to me.

All patients should be made aware of all donor registries upon finding out they need a transplant. There are three reasons we agreed to work with the American Bone Marrow Donor Registry: They agreed to work with us without a down payment; the cost of each bone marrow test is $15 less than Lifesavers'; and Lifesavers never contacted us.

We have determined that there are less than 7,000 African Americans registered as bone marrow donors in the world. We have been told that the odds of an African American finding an unrelated bone marrow donor in the general population of African Americans is one in 20,000. We are trying to add 20,000 African Americans to the donor registries. At $60 per test, the cost would be $1,200,000 to accomplish this.

The burden of raising the moneys to cover this huge undertaking is the responsibility of the Greens, simply because they are trying to save their daughter's life.

The medical technology exists to save Jocelyn or anyone who has a terminal blood disease. Unfortunately, the cost is prohibitive to almost any family wishing to save their loved one. No family should have go to through this. There should be a Government program enacted to cover the cost of testing every American.

Mr. Green told me personally there is not a child or family he would not help if the same circumstances befell them. He already has reached out to other families. No matter the results for Jocelyn, he has dedicated his life to registering donors for everyone, no matter what race, creed, or color.

Throughout all this, Jocelyn's father continues to work on a daily basis for the United States Government and help behind the scenes to save Jocelyn's life. President Bush and Richard Thornburgh, the attorney general, encourage adoption versus abortion. As an employee of the Justice Department, Mr. Green is seeking support from you, the people he works for.

Thank you.

The CHAIRMAN. Thank you very, very much.

I will ask Senator Mikulski to introduce our next witness.

Senator MIKULSKI. Well, thank you, Mr. Chairman.

I would like to welcome both parents and the Atlas family here as well as Ms. Mortensen for the work that she is doing.

Mr. Chairman, in Maryland we have had several people die that have come to our attention while they sought bone marrow transplants. Most recently was Joanne Johnson, an African American, a young woman in Silver Spring, Maryland. Another family in Baltimore. And here today we have the Atlas family, who is fighting mightily to save their daughter. And I would like just to introduce them to you. Mr. and Mrs. Atlas live in Maryland. Their daughter was diagnosed as having leukemia, and their cultural background is Jewish, and when they went to find a bone marrow donor, they found that the resources in the list was far more skimpy than they had originally believed.

They then put out a call for volunteers. But, Mr. Chairman, I think that Mr. Atlas, who will speak in behalf of his family, will tell you that the habits of the heart are alive and well in the United States of America when it comes to finding donors. The habits of the heart are alive and well because one day in one synagogue, 720 people were tested, 400 were turned away not because of a lack of interest but because they just couldn't be processed.

Since then, over 23,000 people have been tested for the Atlas family alone. They are the ones who sought the donors, who set up the programs and so on. He will tell you about their experiences. And I want to welcome him, his wife Arlene, their son Larry, because what they once again are doing while they fight to save their daughter Allison, what they are also doing is leading the way with what the bone marrow program should be.

So, to a dedicated dad and a motivated mom and to all those wonderful volunteers who were willing to not only show up but put up because a bone marrow transplant is indeed a painful procedure to undergo, but they are willing to do it. And what we lack is not the number of people who will volunteer but the wallet to make sure that it's available.

So you are going to hear from a wonderful man who has taken again his personal situation and really made a significant public contribution.

The CHAIRMAN. Mr. Atlas.

Mr. ATLAS. Mr. Chairman, on a hot day last August my daughter Allison fainted while visiting with a neighbor. Almost as an afterthought, she went to the doctor. Two days later we learned the devastating news that she had leukemia. In the weeks that followed, we saw many different doctors. They all said the same thing: There is no therapy for Allison's leukemia but there is a cure, a bone marrow transplant.

Since siblings offer the best chance of providing compatible marrow, Allison's brother and sister were tested. They matched each other, but not Allison. We then tested 100 relatives in our home, hoping to find a matching relative. Still, no match was found.

At that point we were worried but not panicked. The doctors told us that transplants from unrelated donors enjoyed a very high rate of success. They also told us that the National Marrow Donor Program had a registry of 57,000 donors. We were sure that among

those 57,000 there would be a matching donor for Allison. We were wrong. There was no match.

That came as quite a shock to us, but not to the doctors. It was only after searching the registry that we learned that over three-quarters of those who search the registry for a donor come up empty-handed because the chances of two unrelated people having compatible marrow are one in 20,000.

We were told that a registry with 57,000 names was simply too small to satisfy all but a few who depended upon it for their survival. Learning that there was no match for Allison in the registry was a big shock. Learning that the Government has set up the National Marrow Donor Program but had not bothered to provide funds for testing was a much bigger shock.

We did two things: We appealed to the President to apply discretionary HHS funds for testing. We also started testing on our own.

On November 19, 1989, in the Washington suburbs, we held our first mass testing. Friends and relatives put up posters and helped recruit potential donors. We called upon local radio stations to publicize the place and time of the testing. We expected a couple of hundred people to turn out to take the simple blood test that is the first step in determining if someone is a compatible donor. We tested 720 people that day and turned 400 away.

Since that first testing four months ago, we have tested over 23,000 people. Our testing has increased the size of the National Marrow Donor Program registry by over 40 percent. We have not yet found a match for Allison. But we are told that through our efforts have produced over 100 preliminary matches for others awaiting transplants.

We have held testings from Vermont to Florida. Everywhere we go we are greeted with more people who want to be tested than can be accommodated on a single afternoon or evening. The problem is not finding donors, the problem is finding money. Each test costs $75. We have raised and spent $1.5 million. From week to week we never know if we will raise enough money to pay for the tests we have scheduled or will have to cancel them instead. Although we ask for donations from the people we test, we never turn anyone away who is unable or unwilling to pay.

Since we raise at a test site only 15 to 20 percent of the costs of the tests, we have had to go public to raise money. Having a child with cancer is the worst nightmare any parent can imagine. I would do anything to save my daughter's life. But there are no words that adequately express my outrage at having to ask a dying child to do an interview or pose for photographs because her survival and the survival of countless others depends on the contributions generated by media coverage.

I have been told by a member of the board of directors of the National Marrow Donor Program that many of the board members do not feel it is vital to provide funds for testing. Instead, they want to build the registry on the backs of dying children and their families. This is wrong. I don't know how much time Allison has left or if we will find a donor to save her. She should be at home, conserving her strength and spending time with her family, not worrying about raising money and doing interviews.

Before we started testing in November, I wrote the President and asked him to make Federal funds available for testing. In February, he sent us a response, and he said he would be keeping us in his prayers. Prayers alone will not save Allison or the 9,000 people a year who die for lack of a compatible marrow donor.

The President told us in his letter he was directing HHS and the National Heart, Lung and Blood Institute to do everything they could within available resources to assist those needing a marrow donor. The bureaucrats wasted no time coming up with a disappointing response. Three days after the President' letter, the director of the National Heart, Lung and Blood Institute, Dr. Claude Lenfant, wrote Bart Fisher, who is a member of the board of the National Marrow Donor Program, to inform him that no NIH funds were available for testing. And Secretary Sullivan has not even bothered to respond to a letter from Senator Mikulski asking for help.

Unless Congress takes matters into its own hands, things will get worse before they get better. Before a recent meeting of the board of directors of the National Marrow Donor Program, Dr. Lenfant told the board that their budget would be frozen at $3.6 million and that the $2 million that the board had expected to be made available by NIH for testing would not be forthcoming. In fact, Lenfant also eliminated from next year's budget the $90,000 that had been made available this year for minority testing.

Marrow transplants are a proven, cost-effective cure for several types of leukemia and other blood diseases. Years of Government-funded medical research has perfected this procedure to the point where it can be applied on a large scale. Congress funds billions of dollars of medical research through NIH each year in the hopes of developing and perfecting breakthroughs like marrow transplants. What is the point of giving NIH all that money if the agency is unwilling to commit a small fraction of those funds to making these breakthroughs available to the people who need them?

In the past several months, we have been in contact with several other families who are looking for donors. In the past month alone, four of those families ran out of time and had to bury a loved one. Meanwhile, the National Marrow Donor Program and the regional centers which feed data into the system have failed to gear up the process of donor information that our drives have been generating.

Since the beginning of March, I have received calls from ten people who were tested at our first drives which occurred in mid-November. They call to say that they have just been called back in for further testing because they were potential matches for people needing transplants. These people were elated because they want to be donors. I was horror-stricken because over three months had elapsed between the time they were tested and the time their names and typing entered the system.

I called Dr. Lenfant. He told me that the ten people I was referring to have been in the system for some time. He said they were now being called back in for further testing because they all turned up as potential matches for one new leukemia victim who had just initiated a search. That cannot be the case. All ten of these people have very different typing.

Delays are occurring, and these delays are killing people. I wish I was eloquent enough to express the anguish I feel when I think of dying children and young adults and piles of unprocessed test results sitting on a floor somewhere for want of clerical help to process the data. The extremely small staffs at NIH, the other local donor centers, and the National Marrow Donor Program who are responsible for entering the data and calling people in for further testing are working heroically to keep up. But they are simply overwhelmed. They need help, and they need it now.

There is talk of instituting the use of scanning equipment to speed up the process. But that is months or maybe years away. Meanwhile, 25 people a day die whose lives could be saved. To create the National Marrow Donor Program without funds to test donors is to create nothing more than a cruel illusion. You can make this program work only by appropriating emergency funds for testing. You can make this program work only by insisting that NIH use a small fraction of the billions you gave them to make the miracle of a marrow transplant available to the 9,000 people a year who need one in order to live.

Finally, you can make this program work only by requiring the National Marrow Donor Program, NIH, and the donor centers to immediately staff their operations with enough people to put donors into the system without any delay. I beg you to do something to save these people. They are so close to a cure and yet so close to death. You are their only hope.

Thank you very much.

[The prepared statement of Mr. Atlas follows:]

PREPARED STATEMENT OF ALVIN S. ATLAS

On a hot day last August, my daughter Allison fainted while visiting with a neighbor. Almost as an afterthought, she went to the doctor. Two days later we learned the devastating news that she had leukemia.

In the weeks that followed we saw many different doctors. They all said the same thing. There is no therapy for Allison's leukemia, but there is a cure -- a bone marrow transplant. Since siblings offer the best chance of providing compatible marrow, Allison's brother and sister were tested. They matched each other -- but not Allison. We then tested a hundred relatives in our home, hoping to find a matching relative. Still no match was found.

At that point we were very worried, but not panicked. The doctors told us that transplants from unrelated donors enjoyed a very high rate of success. They also told us that the National Marrow Donor Program had a registry of 57,000 donors. We were sure that among those 57,000 there would be a matching donor for Allison. We were wrong. There was no match. That came as quite a shock to us, but not to the doctors. It was only after searching the registry that we learned that over three-quarters of those

who search the registry for a donor come up empty- handed. Because the chances of two unrelated people having compatible marrow are 1 in 20,000, we were told that a registry with 57,000 names was simply too small to satisfy all but a few who depended upon it for their survival.

Learning that there was no match for Allison in the registry was a big shock. Learning that the Government had set up the National Marrow Donor Program but had not bothered to provide funds for testing was a bigger shock. We did two things. We appealed to the President to apply discretionary HHS funds for testing. We also started doing testing on our own.

On November 19, 1989 in the Washington suburbs we held our first mass testing. Friends and relatives put up posters and helped recruit potential donors. We called upon local radio stations to publicize the place and time of the testing. We expected a couple of hundred people to turn out to take the simple blood test that is the first step in determining if someone is a compatible donor. We tested 720 people that day; and turned another 400 away.

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our efforts have produced over 100 preliminary matches for others awaiting transplants.

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Each test costs $75. We have raised and spent over $1.5 million. From week to week we never know if we will raise enough money to pay for the tests we have scheduled for the following week or will have to cancel them instead. Although we solicit donations from the people we test, we never turn away anyone who is unable to pay for his or her test.

Since we raise at a test site only 15% to 20% of the cost of the tests, we have had to "go public" to raise money. I would do anything to save my daughter's life. But there are no words that adequately express my outrage at having to ask a dying child to do an interview or pose for photographs because her survival (and the survival of countless others) depends on the contributions generated by media coverage.

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for testing. Instead, they want to build the registry on the backs of dying children and their families. This is wrong. I don't know how much time Allison has left or if we will find a donor in time to save her. She should be at home conserving her strength and spending time with her family; not worrying about raising money and doing interviews.

Before we started testing in November I wrote the President and asked him to make federal funds available for testing. In February he sent us a response and said he will be keeping us in his prayers. Prayers alone will not save Allison or the 9,000 people a year who die for lack of a compatible marrow donor.

The President's letter (See Attachment A) refers to people with "uncommon tissue types for whom matches have not yet been found." There are thousands of tissue types; all are uncommon and only a fraction of people needing donors find a match in the present registry.

The President's letter refers to the need for laboratories in addition to funds and implies that money alone will not solve the problem. He is wrong. The laboratory capacity exists -- we can test 2,000 people a week at our own drives without difficulty and have doubled the number on at least one occasion.

The President told us in his letter that he was directing HHS and the National Heart, Lung and Blood Institute to do everything they could within available resources

to assist those needing a marrow donor. The bureaucrats wasted no time coming up with a disappointing response. Three days after the President's letter, the Director of the National Heart, Lung and Blood Institute, Dr. Claude Lenfant, wrote Bart Fisher, a member of the board of the National Marrow Donor Program, to inform him that no NIH funds were available for testing. (See Attachment B)

Unless Congress takes matters into its own hands things will get worse before they get better. Before a recent meeting of the Board of Directors of the National Marrow Donor Program, Dr. Lenfant told the Board that their budget would be frozen at $3.6 million and that the $2 million the Board had expected to be made available by NIH for testing would not be forthcoming. In fact, Lenfant also eliminated from next year's budget the $90,000 that had been made available this year for minority testing.

Marrow transplants are a proven, cost-effective cure for several types of leukemia and other blood diseases. Years of government funded medical research has perfected this procedure to the point where it can be applied on a large scale. Congress funds billions of dollars of medical research through NIH each year in the hopes of developing and perfecting breakthroughs like marrow transplants. What is the point of giving NIH all that money if the agency is unwilling to commit a small fraction of those funds (less than 10 cents per American) to making these breakthroughs available to the people who need them?

In the last several months we have been in contact with several other families who are looking for donors. In the past month alone four of those families ran out of time and had to bury a loved one. Meanwhile the National Marrow Donor Program and the regional centers which feed data into the system have failed to gear up to process the donor information that our drives have been generating. A recent Office of Technology Assessment Staff Paper stated that "a long lag may occur" before donor typing obtained through mass testings are entered into the computer system. (See Attachment C). Dr. Lenfant's February 9, 1990 letter to Bart Fisher contains a similar statement.

Since the beginning of March I have received calls from ten people who were tested at our first drives, which occurred in mid-November. They called to say they had just been called back in for further testing because they were potential matches for people needing transplants. These people were elated because they want to be donors. I was horror-stricken because over three months had elapsed between the time they were tested and the time their names and typing entered the system. I called Dr. Lenfant. He told me that the ten people I was referring to had been in the system for some time. He said they were now being called back in for further testing because they all turned up as potential matches for one new leukemia victim who had just initiated a search. That cannot be the case -- all ten of these people have markedly different typing.

Delays are occurring and these delays are killing people. I wish I was eloquent enough to express the anguish I feel when I think of dying children and young adults -- and piles of unprocessed test results sitting on a floor somewhere for want of clerical help to process the data. The extremely small staffs at NIH, the other local donor centers and the National Marrow Donor Program who are responsible for entering the data and calling people in for further testing are working heroically to keep up -- but they are simply overwhelmed. They need help and they need it now. There is talk of instituting the use of scanning equipment to speed up the process. But that is months or years away. Meanwhile 25 people a day who could be saved die needlessly.

To create a National Marrow Donor Program without any funds to test donors is to create nothing more than a cruel illusion. You can make this program work only by appropriating emergency funds for testing. You can make this program work only by insisting that NIH use a small fraction of the billions you give them to make the miracle of a marrow transplant available to the 9,000 people a year who need one in order to live. Finally, you can make this program work only by requiring the National Marrow Donor Program, NIH and the donor centers to immediately staff their operations with enough people to put donors into the system without any delay.

I beg you to do something to save these people. They are so close to a cure and yet so close to death. You are their only hope.

ATTACHMENT A

LETTER FROM PRESIDENT BUSH TO ARLINE AND ALVIN ATLAS DATED FEBRUARY 6, 1990

THE WHITE HOUSE

WASHINGTON

February 6, 1990

Dear Mr. and Mrs. Atlas:

Your letter about the illness of your daughter, Allison, and her need for someone to donate marrow for her has greatly touched Barbara and me. From our own experience, we understand the anguish of a family when a child is diagnosed with leukemia. We sincerely hope that she can hold on until an acceptable donor is found.

The scientists at the National Institutes of Health tell me there has been a rapid increase in the number of marrow donors listed in the Registry of the National Marrow Donor Program, with the number more than tripling in the last year. It is very gratifying to see the large number of Americans of all races and all walks of life who are coming forward to be HLA-typed and listed in the Registry. Nevertheless, we feel a great sadness for those with uncommon tissue types for whom matches have not yet been found. The resources necessary to expand the volunteer marrow donor base involve not only funds but also laboratories to perform the needed tests with great professional skill. The National Heart, Lung and Blood Institute, one of the National Institutes of Health, is working with the National Marrow Donor Program to increase the resources available for the very costly HLA-typing tests.

I am relaying your plea to the leadership of the Department of Health and Human Services and to the National Heart, Lung and Blood Institute, asking them to do everything they can within the available resources to assist those, such as your daughter, in finding the needed donor.

We will be keeping you in our prayers.

Sincerely,

George Bush

Mr. and Mrs. Alvin Atlas
7600 Arrowood Road
Bethesda, Maryland 20617

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

National Institutes of Health
National Heart, Lung, and
Blood Institute
Bethesda, Maryland 20892

Fax (301) 402-0818

ATTACHMENT B

LETTER FROM CLAUDE LENFANT, M.D. TO BART S. FISHER
DATED FEBRUARY 9, 1990

February 9, 1990

Bart S. Fisher
Patton, Boggs & Blow
2550 M Street, N.W.
Washington, DC 20037-1350

Dear Bart;

As I mentioned in my January 29 letter to you, I wanted to give your request the fullest consideration and promised to contact you once we looked into the matter of additional funds for tissue typing in more detail. I am writing this letter to share with you our perspective on this matter.

First, please be assured that the Institute fully supports the need to increase the number of donors in the National Marrow Donor Program (NMDP) registry. As I see it, the challenge that faces us now is how to handle the "operational" issues, i.e., how to support the costs of an increase and the resulting increased demand for typing.

As you know, the Institute concurred in the recent decision to raise the NMDP registry goal from 100,000 to 250,000 donors. In order to accomplish this, we have estimated that approximately $11.25M would be needed for HLA-A and -B typing alone; and that adding DR typing would cost twice this amount. Thus, an additional $4M for typing would be a significant contribution. Unfortunately, because of the current fiscal constraints under which we are operating, there are no funds available in the Institute budget that can be reallocated at this time. Even with additional funding, it will be important to avoid exceeding the typing capacity of donor centers, as has been the case in some recent individual cases with which you are no doubt familiar.

I regret it is not possible for me to provide a quick or easy solution to this very important problem. However, we fully recognize the need for additional funds, and if resources can be provided from other than the current NIH budget, the Institute would work closely with the NMDP to assist in their appropriate use.

I very much appreciate your tireless efforts on behalf of this program. If you have any further comments or questions, please do not hesitate to contact me again.

With best regards, I am

Sincerely yours,

Claude Lenfant, M.D.
Director

The CHAIRMAN. Thank you very much, Mr. Atlas, for your reminder for us about a sense of humanity and decency, of what we think is important and what we don't. I think you will find that the members of this committee will do everything that we possibly can. And I say it for all of the members of the panel, that is probably the only way that we can ever express our appreciation enough for all of your presentations this morning.

Ms. Kathy Barrett is a single parent, mother of one child, Diana, who is seven and a half. Kathy is a paramedic in Alexandria and lives in Woodbridge, Virginia. Diana was diagnosed with leukemia last fall. Ms. Barrett will describe her experience trying to find a suitable donor for her child. And because of both the nature of her responsibilities as a paramedic in Virginia, she has not had the kind of strong community that Joanne Johnson or Allison Atlas has had, and finds herself unable to have the kind of public campaign that the families of these other two have been able to undertake. So the Barretts are similar to more than 9,000 who are searching for donors and whose names have not shown up in the major press.

We are very appreciative for your presence here. We look forward to your testimony.

Ms. BARRETT. Good morning, Mr. Chairman, other members of the committee. My name is Kathleen Barrett. My daughter, Diana Williams, is seven and a half. She was diagnosed with ALL on September 1. I had taken her in for her school checkup before she started second grade. She was perfectly healthy, looked good, felt good. And within 5 minutes they had diagnosed the fact that she had a white cell count of over 66,000, and she had a grossly enlarged liver and spleen, although she showed no symptoms, no outward signs. By that evening we had gone to four other blood testing labs throughout northern Virginia because no one could believe that she had that advanced case of leukemia, looking at her the way she did. She is very tall; she was very tan. She felt fine; she had no complaints.

By the end of the day, I had reached home and had messages on my answering machine from three different doctors—two of them I didn't even know—saying that I needed to get Diana to Fairfax Hospital immediately.

I called one of them back and I said, you know, she's been through an awful lot today, to have a 7-year-old constantly stuck with needles it got to the point where she had to be held down. She couldn't tolerate it. I said can't we wait till the morning and bring her in, and they said no, it cannot wait. So I brought her in to Fairfax Hospital, where they did a bone marrow tap right there up on the fifth floor and found that she had over 90 percent cancerous cells throughout her body.

So she was hospitalized for the first 12 days. She had a central line put in her chest, which is much easier. Some of the older children don't have that done and they have to repeatedly be stuck with IV's. For the younger children it's a real blessing. They get all their medication given through this IV site right into their heart and blood taken out on a daily basis, and there is no pain involved. It's just a matter of cleaning it and taking care of it.

We went through the standard acute lymphocytic leukemia protocols for the first three weeks. Normally, children with a run-of-the-mill ALL will go into remission quite easily, two to three weeks. After a month of her protocols, Dr. Jay Greenburg, who is her physician, found that not only did she not go into remission but she also had some cells of AML, which is another type of leukemia. And we were going to have to switch protocols and go into a high-risk ALL protocol.

We switched over to AML protocols and went for another month in this very high-intensive chemotherapy, which caused her to be violently ill, to have neurological deficits, to develop diabetes. She lost a lot of weight, had a lot of problems. At the end of October he said that although she had seven percent active cancer cells still showing, she was technically in remission. We started October 2 looking for a bone marrow transplant donor.

When he felt that she did not go into remission immediately with the standard ALL protocols, he spoke to a panel of doctors which were comprised of Johns Hopkins, Sloan-Kettering, Children's Hospital, Fairfax Hospital, and another one, that got together and decided the best place for a nonrelated donor bone marrow transplant for Diana's particular case would be Children's Hospital, Milwaukee, Wisconsin.

Her case was referred to them, and that afternoon probably about 15 minutes after he got off the phone telling me for the first time that Diana needed a bone marrow transplant, Milwaukee called and said, okay, we need all this information, we're going to start processing you for a transplant.

So I gave them all the information they wanted, nine tubes of my blood, nine tubes of her father's blood. Diana is a single child. She was my only child. So there is no sibling match. There was no one to be tested. Her father was tested. I was tested. We were both equal half-matches, which is really not good enough for a full transplant, and especially in Diana's case. So we have been looking since October 2.

Children's Hospital, Milwaukee, has been handling national registry, American registry, the Caitlin Raymond registry, and they check it on starting on a daily basis and it got to a weekly, it got to a monthly. And I just spoke to them last week, and they have started to send me the bills. They said that they really feel that after 6 months' worth of looking, they don't feel that they are going to find a perfect bone marrow transplant donor for Diana. She has a rare typing; she is one of those children who do. There is a possibility of a mismatch if things get bad. She is at the end of her protocol. She has been given every chemotherapy available for her case without causing permanent damage. And we are at the end of the line. Next week will be the last treatment of chemotherapy, and we need to make a decision. There is still no donor available. So we are still looking.

She is unable to be with me today. She really wanted to come, but she was put into the hospital yesterday evening with high fever and neutropenia. So she is unable to be with me today. And that is where we are, short and simple.

I have gone through everything that Mr. Atlas has gone through and the Green family, with talking to Lifesavers. The only thing

they could do was to set up donor sites where they could test people, and again it's $75 a test. I am a single parent on a public servant's salary. I can't do it. I just can't physically do it. I don't have the money. My insurance company refused to pay for the transplant or the donor search. They said—they agreed to pay and then they turned around and said that they didn't realize how expensive it was, that we're talking about a $200,000-plus operation along with the donor search. I don't have that kind of money.

So my fire department has been raising the money. They have raised for me over $20,000. These are fire fighters, paramedics, the officers, the public that we take care of every day and the city of Alexandria, Woodbridge residents and that is the money that has to go to just paying for the donor search, which is $20,000. They have utilized everything they possibly can as far as donor searching in Diana's behalf in the registry. They have found nothing.

So there is a possibility, the hospital that Joanne Johnson was taken to in Kentucky may be able to do a mismatch if we can come up with even a four out of six match is as low as they will go. And so we are considering Kentucky if we can find somebody who just has four of the components out of the six. Then we will go for that.

The CHAIRMAN. Well, it is admirable that your associates in the fire and police department are willing to help. That is a great aspect of the American character. But I mean to have the dependency, the burden put on you to try to deal with these financial burdens, I find unconscionable, myself.

Let me just ask each of the members of the panel, what do you find when you enter the system, from your own life's experience, all of you, what are the things which are really the most troublesome?

I mean it is obviously the anxiety for the child, clearly.

But what are the things which are the most frustrating? What sort of insight could you give us as we redraft the legislation to try to come to grips with this?

Let me start on the left to right. Maybe I am asking for a simple answer to a complicated issue, but give us some help on that.

Ms. MORTENSEN. I think we need to educate the American public that it is so simple to do a bone marrow test. But raising the funds to do this has been unbelievable. We are still $8,000 in debt, and we have only tested 300 people. And we have nine more sites set up, and we don't have the funds to pay for them, sir.

Hopefully, enough people will donate, but like our fundraiser tonight you are invited to, we have to do things like that all the time to try to raise the funds to pay for it.

And there is a price put on every child's head. A child shouldn't be a wanted poster with a price on it.

The CHAIRMAN. Mr. Atlas?

Mr. ATLAS. I think when we first go into the system, the patients are not given enough information. I know my family first found out that there was no treatment for my daughter's type of leukemia but there was a cure and there was this registry with 57,000 names. We just thought it would be automatic that we would have a donor. We weren't overly concerned at the time.

I think more information has to be given to the patients, what they're up against. I also think the public has to be educated be-

cause even today it's referred to as an operation, and it's not an operation. There is absolutely no cutting. It is a very simple procedure. It is like a blood transfusion.

My daughter, when it happens, will be awake for the four hours of the transfusion. And it's not like donating an organ, because you're not giving up anything. Your marrow replenishes within two weeks. And I think the public has to know these things. These were some of the obstacles we had in the beginning, but the donors are out there, they are willing to come forth. It's just the money. That's the big problem.

The CHAIRMAN. I think the point that you mentioned earlier, which I think deserves underlining, is the enormous sense of satisfaction that these donors have when they find that they are finally called upon to provide the marrow for that other individual. The very real sense they are absolutely giving life this, and the extraordinary sense that you have mentioned here is something which is important for all of us to understand.

Maybe you would elaborate on that.

Mr. ATLAS. I have met so far four people who have been donors who have had the opportunity to give their marrow, and they said it's the greatest experience of their life to know that they alone are responsible saving somebody's life. They said, "How many people in their life get that type of opportunity." And all of them say that they would more than be willing to do it again. It's a great experience for them.

The CHAIRMAN. Ms. Barrett?

Ms. BARRETT. Public awareness is definitely number one, getting the people to the sites, having it funded and not by the families, those of us who are unable to handle that staggering amount of money and therefore our child should not be able to get a transplant just because we can't afford to pay for the people to get tested is not right. Getting it out and getting it publicized, explaining that it is not a painful procedure, explaining that you are saving a human life, a child's life, someone who hasn't even had a chance to live their life yet is very important.

The insurance was my biggest stumbling block. My particular insurance company is the average HMO, which a lot of people have in big businesses and corporations, and several times the paperwork and things that happen, we were told, yes, they pay for everything, then we were told no, they don't pay for the donor search. Then we said that they will raise $20,000, pay $20,000 for the donor search, they said you need it up front. Where do we get $20,000?

So we handled that, and then we were told, well, no, they don't pay for bone marrow transplants. They will pay for your hospital bed, but they don't pay for anything else. And we also found you have to cover the donors' transportation, everything that has to do with the donor as well as the entire procedure and the hospitalization. And the amount is about $200,000 to $250,000 per transplant, and that is with no complications. If there is extended period or complications with the patient, the figures are staggering. Getting the donors to the banks and getting them registered and getting them in is number one. Like Mr. Atlas, they told me in October that Diana needed a transplant, and they said, "Well, we've got 100,000 here, you've got 50-something there, you've got all those

people," and automatically I assumed, okay, there is somebody out there that is a perfect match. But it's been over six months. There is nobody, and Diana is running out of time.

The CHAIRMAN. Well, it's the funding, obviously, because you have to get the typing initially, and then once you begin to narrow this phrase to do the second kind of testing to find out whether that transplant, that runs $75 for the first and somewhat close to $150 for the second. And you don't know in that second test how many you're going to have to run through till you get the one that's going to be able to be the match.

But you do know if you do provide the kind of investment in that and try that to review, that you can meet the overwhelming majority of the cases that are affecting American families. I mean you know that with an investment of a certain amount of resources, I mean that's just there. And, you know, it's basically just social insurance.

My son had the kind of cancer in his leg, it was one in five million. We as a society ought to know that we're going to have a certain number of our fellow population who are going to have this problem. We could say, well, be thankful that it isn't my family, but we're glad to make some kind of contribution so if the other families are affected, they're going to be able to get treatment. And that's what basically caring about our fellow human beings and being, I think, a civilized society is about.

Thank you very much.

Senator KASSEBAUM. Well, I don't really have anything to add other than I think it has been very moving and very important testimony. It is so often, as you point out, many don't even realize what one must go through.

I guess I would just like to ask you, Mr. Atlas, because you have spent a lot of time and have raised a considerable amount of money and put a great deal of effort into initiating a large number of tests, how many did you say?

Mr. ATLAS. A little over 23,000.

Senator KASSEBAUM. Which is really quite extraordinary.

What are you doing with those names and those tests that you have done now?

Mr. ATLAS. They go into the National Marrow Donor Program.

Senator KASSEBAUM. Into the registry?

Mr. ATLAS. That's correct.

Senator KASSEBAUM. Well, it just seems to me at some point this is the contribution, of course, that has to be recognized, and I think that again this is where the coordination of all of these tests that are being done have to be recognized, have to be supported and I think can be supported.

I was interested in the comment about setting up your own site. I would just like to ask, can you, even with your own resources, use an already established site? Why, for instance, would you have to set up your own?

Ms. MORTENSEN. You find places to hold the blood drives, then contract with the lab to come in. And hopefully, people will step forward and volunteer places to hold blood drives. We have had three, and we have nine more set up.

Senator KASSEBAUM. Can you use a Red Cross site, for instance?

Ms. MORTENSEN. Not that I know of.

Mr. ATLAS. Senator, I can tell you that we have absolutely no problem getting sites. We get phone calls from all over the country, people that are willing to give us places to do testing and to help us. We just don't have enough money to go every place. Right now we do about 2,0000 tests a week. That is $150,000 a week we're spending. And we could do more.

Senator KASSEBAUM. Well, I can understand that. I just didn't know if there were already those equipped to do the testing, whether it's a Red Cross site or whatever.

Ms. MORTENSEN. You can do it one or two at a time, but they don't do massive testing like we need to find a donor.

Senator KASSEBAUM. Thank you very much. I appreciate it very much.

The CHAIRMAN. You complicate the problem because a lot of people come on in all at the same time. You may have hard workers and they come on in and get out of work, have a couple of hours, and then they've got to go back and cook for their kids. You've got a limited period of time, too. This isn't really structured or organized.

OK. Well, as I say, we will do everything we can to get those resources. That is the only way we can really express our appreciation enough.

Mr. ATLAS. Thank you very much.

The CHAIRMAN. Thank you very, very much.

Ms. MORTENSEN. Thank you.

Ms. BARRETT. Thank you.

The CHAIRMAN. On our final panel today are experts involved in the bone marrow transplant system. The first witness of the third panel is Dr. Claude Lenfant. Dr. Lenfant is the director of the National Heart, Lung and Blood Institute, which runs the contract for the National Marrow Donor Program.

Dr. Lenfant, we welcome you and we will look forward to your testimony.

Then we will go to Ms. Joan Keller, who is the president of the American Bone Marrow Donor Registry.

Ms. Keller, we will look forward. We know you have traveled a long way. And accompanying you, as I understand, is Joann Raymond, who is the secretary of the American Registry. Ms. Raymond is also the executive director of the Caitlin Raymond International Registry of Bone Marrow Donor Banks, the coordinating center for the American Registry, located in Worcester, Massachusetts. I am familiar with it.

Then we will have Dr. Robert Graves, the vice chairman of the board of directors of the National Marrow Donor Program. Dr. Graves has been involved in the issue probably longer than any of us. We look forward to hearing from him.

Dr. Lenfant.

STATEMENTS OF DR. CLAUDE LENFANT, DIRECTOR, NATIONAL HEART, LUNG, AND BLOOD INSTITUTE, BETHESDA, MD; JOANNE KELLER, PRESIDENT, AMERICAN BONE MARROW DONOR REGISTRY; ACCOMPANIED BY JOANN RAYMOND, SECRETARY, AMERICAN BONE MARROW DONOR REGISTRY, MANDEVILLE, LA; AND DR. ROBERT GRAVES, VICE CHAIRMAN, BOARD OF DIRECTORS, NATIONAL BONE MARROW DONOR PROGRAM, ST. PAUL, MN

Dr. LENFANT. Thank you, Mr. Chairman.

I have submitted a written statement which I would very much like to include for the record.

The CHAIRMAN. All the statements will be included in their entirety.

Dr. LENFANT. Let me just add a few points to my statement.

As you may know, Mr. Chairman, the institute has been responsible for this program for just about one year. Since we have worked diligently with the National Marrow Donor Program to foster their growth, we have, I should say, a very keen interest in this program for its humanitarian goals and also for the research opportunities which it gives us.

We are, of course, very much aware of the problems which have been mentioned earlier, problems related to cost of typing, laboratory capacity, and recruitment of minorities and other ethnic groups.

We are working with the National Marrow Donor Program to solve these problems, and we have been working with the different registries to achieve a coordination for we do indeed believe that such a coordination would serve the American people much better than by having divided programs.

I would like, for the sake of time, Mr. Chairman, to stop my remarks here, and I would be pleased to answer your questions when you wish.

The CHAIRMAN. I think since we have somewhat different approaches on this, I think we will inquire briefly of each witness and then move down.

Dr. Lenfant, as I understand, there is no increase in the amount of funds for the bone marrow registry for the next fiscal year over that allocated in 1990. Is that true?

Dr. LENFANT. Not so, Mr. Chairman. The budget allocated to this program for the current fiscal year is $3.6 million. For next year the budget, which is the estimated budget, will be either $4 million or $3.9 million. So it is a small increase, but there is an increase.

The CHAIRMAN. Well, does that represent current service? Does that just about cover the increase in inflation?

Dr. LENFANT. It pretty much corresponds to current services.

The CHAIRMAN. So that effectively you are able to do about what you were able to do a year ago? Is that it?

Dr. LENFANT. Just about. Just about, sir.

The CHAIRMAN. So if it's current services, there is no real effective increase in the budget. I don't want to wrestle around with the meaning of words. But under the NIH contract, I understand that only $400,000 has been specifically allocated for typing.

Dr. LENFANT. For this current fiscal year the amount which will be in fact spent for typing—that is, 1990—it will be almost $1.2 million. $400,000 coming from the contract and $800,000 coming from the cost reimbursements.

The CHAIRMAN. Well, the reimbursements, but in terms of the contract itself, it's $400,000?

Dr. LENFANT. That's correct.

The CHAIRMAN. Out of the $3.6 million.

Now, do you expect that this part of the current contract will be modified in the near future to reflect the growing concern that more money needs to be available for typing?

Dr. LENFANT. We are working with the board of directors of the National Marrow Donor Program to redistribute as much funds as possible for the HLA typing. How successful we will be it is difficult to say at this time. You may know, Mr. Chairman, that the contract is in the process of moving from the National Red Cross, which is now the contractor, to a new organization which will become responsible for the program, and we expect to be working much more closely with them than we were able to do it in the past.

The CHAIRMAN. Well, in terms of the priority that you give the typing, aren't you the one that makes that recommendation or decision?

Dr. LENFANT. So far, no. But we do intend to assume that responsibility. And I say so far, no, because when the contract was transferred from the Navy a year ago, at that time the negotiation with the Navy, which we have continued what had been agreed with the Navy, included a very small fraction of the total budget for typing. We were, if you want, locked into that situation.

The CHAIRMAN. Well, can you tell us or give us some idea as to what kind of increase you are going to recommend for typing?

Dr. LENFANT. We would like to see approximately between 20 and 25 percent of the budget that we have to go to typing, which would be in the order of approximately $900,000.

The CHAIRMAN. Why? Why do you think that there should be a doubling of it?

Dr. LENFANT. Because it is obviously a very important issue. It's very clear from what you have heard earlier that the previous goal of 100,000 names in the registry is not sufficient to meet the needs. The program has set for itself new goals, which is 250,000 names into the registry. The cost to go from 100,000 to 200,000 is in the order of $11 million to $12 million for just one typing. If you do the two typings, you would have to double this amount.

A budget of $4 million will not allow to do that, but the fact that we need to utilize as much money as we can from the contract to contribute to that typing affords. The rest of the money is necessary for the maintenance of the registry, for the donor centers, and for the transplantation centers, the costs which are related to these activities.

The CHAIRMAN. Did you make a recommendation to OMB?

Dr. LENFANT. No. We did not. We made a recommendation for the entire budget of the institute, but not for this specific activity.

The CHAIRMAN. Well, for the total increase for the institute, did you have an increase?

Dr. LENFANT. The budget of the institute in 1990, fiscal year 1990, is $1,050,000,000.

The CHAIRMAN. $1,050,000,000?

Dr. LENFANT. $1,050,000,000.

The CHAIRMAN. Right.

Dr. LENFANT. For 1991, the President's budget is $1,090,000,000. That is not the professional judgment which we submitted. That is the beginning of the budget process.

The CHAIRMAN. What was the recommendation? Can you tell us?

Dr. LENFANT. It was $1.4 billion.

The CHAIRMAN. If you had been able to get the $1.4 billion, how would this have reflected itself in this function?

Dr. LENFANT. We would certainly allocate a considerable amount of money to the typing. Whether we would be able to allocate the $22 million which are necessary to go from 100 to 200,000, I don't know and I do not believe that that amount could really be spent in one year because of the laboratory capacity to handle such a large number of samples.

The process of these typings is not just as simple as many people might believe. But we would certainly allocate a considerable amount of money.

The CHAIRMAN. How many donors on the current national registry would you estimate come as a result of individual drives?

Dr. LENFANT. Well, as you heard from Mr. Atlas, the drives for his daughter have brought into the registry approximately 23,000 names. For the other local situations, Mrs. Johnson, that has brought approximately 1,000 or 1,200 names of minorities, so that today we can say that the number of names of minority donors that we have in the programs is in large part due to the Johnson family drives.

The CHAIRMAN. Well, are you giving any special consideration because the registry has such an apparent shortage of minorities?

Dr. LENFANT. Yes. Yes, sir. In fact, we are now preparing to initiate a number of special activities to enhance the recruitment of minorities. In fact, I have just last week reallocated money from other programs to the special recruitment and education effort in the minority communities in order to increase the number of donors.

As you know, Senator, we do have a number of programs relative to high blood pressures, which is extremely prevalent among the black Americans, and we are going to merge the bone marrow recruitment effort with education campaigns relative to high blood pressure directed to minorities in order to reach the black communities.

One of the problems that we have is that much has been said about these programs by way of national news, national newspapers and media which really does not reach the minority community. What we are going to do is to utilize the electronic and printed media which is specially directed to the minority communities.

The CHAIRMAN. Well, we are going to be very interested in following that.

What are you doing to bring about greater coordination between the various registries?

Dr. LENFANT. In its appropriation report for this fiscal year, the Congress directed me to work on bringing together all the regis-

tries, and I believe we have met the wish of the Congress in the sense that I have held a meeting with the independent registries, of American registries, and I have had many discussions with the board of the national program.

I have asked the American registry to stay in touch with me and let me know if the discussions that they had with the national program were not as successful as they wanted, and thus far I haven't received any feedback to that effect. And I know that in effect the two groups are working together much better today than they were a few months ago. In fact, some of the independent registries, some of the most important with the largest number of donors, have now joined forces with the national programs, and I believe that with time we will have a unique, consolidated program in the country.

The CHAIRMAN. Well, I think you have been able to detect that is certainly an objective which I think the Members of Congress want to see. And I, quite frankly, would like to have you submit in greater detail how specifically these meetings, conversations, whatever is happening, how they are getting out into the grass roots, how this is explicitly being achieved.

Dr. LENFANT. I will submit that for the record.

The CHAIRMAN. If you would, so that we will know that this is not something that is left at random but is something that is actually incorporated. I would like to have that in whatever detail you can provide, and then we will get back to you.

Dr. LENFANT. I will submit it, sir.

The CHAIRMAN. Thank you.

[The information of Dr. Lenfant follows:]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Heart, Lung, and
Blood Institute
Bethesda, Maryland 20892

Fax (301) 402-0818

March 26, 1990

The Honorable Edward M. Kennedy
United States Senate
Washington, D. C. 20510-2101

Dear Senator Kennedy:

During the hearings on the "Bone Marrow Transplantation Program Reauthorization" you held on March 21st, you asked me to provide additional information about two questions.

- The role of the National Heart, Lung, and Blood Institute (NHLBI) in resolving differences between the American Association of Bone Marrow Donor Registry (AABMDR) and the National Marrow Donor Program (NMDP). The latter is supported by Federal funds by way of a contract with NHLBI.
- Clinical trials conducted under the auspices of the NMDP.

In the following I would like to address these two questions:

AABMDR and NMDP

Well before the NHLBI became responsible for the administration of the NMDP in March 1989, it was aware of issues separating the NMDP and AABMDR. These issues are:

- cost of the search process,
- payment for the care of indigent patients, and
- patient access to the NMDP registry.

Through "behind the scene" interventions and direct discussions with each of the organizations, we have assisted in the partial resolution of the issues.

Each search incudes a preliminary phase, followed by a formal phase, if an HLA-A and B match has been identified. AABMDR has a fee to start a preliminary search, but no additional fee is requested for a formal

search. In contrast, NMDP has no fee for the preliminary search, but has one for the formal phase. The main problem is that some transplant centers "accredited" by NMDP have, up front, a down payment charge which sometimes exceeds $10,000. Because the Institute has no leverage on these transplant centers, we have not been in a position to intervene on this issue.

Actually this issue is intertwined with another major issue concerning the identification/selection of the transplant centers. The NMDP will provide names of donors only to centers that it has accredited. This accreditation is based upon evidence that a marrow transplant unit is fully functional as a unit, has appropriate facilities, and they have had adequate experience as defined by the number of allogeneic transplants that have been performed prior to accreditation. Originally the NMDP required 25 allogeneic transplants yearly for two years to be eligible for accreditation. Because the AABMDR objected so strongly to these criteria which were arbitrary when established, the Institute has intervened to modify them. As a result, the current standard is 10 allogeneic transplants annually for two years and at least 30 in the previous five years. It is our opinion that these criteria are an appropriate compromise between the need to augment the number of centers and that of protecting the well being of donors and recipients.

I must underscore that this issue is an extremely important and sensitive one. During the hearings, the AABMDR representatives mentioned the plight of potential transplant patients in Louisiana. In that state, there is no NMDP participating center; there are only two small transplant units. As a consequence, indigent patients who could be supported by the state, but in that state only, do not have the benefit of the donors listed in the NMDP registry. This is an issue that the Institute wants to address and will do so as soon as possible.

Corollary to the above concern, is the issue of who decides what transplant center is appropriate. The AABMDR argues that the NMDP Board presides over all the decisions—in effect as judge and party—without the check and balance that would result from an independent review of the decision made by NMDP. This is the reason the Institute will create a Policy Committee that will review the NMDP actions and advise the Institute accordingly.

In June of last year, I personally met with the leadership of AABMDR to offer my service as an ombudsman of sort, to resolve differences between the two organizations. In August, I was informed by letter from the Executive Director of AABMDR that they had received a new draft of a proposed agreement with NMDP. The letter said "There are some minor issues that need to be resolved within the AABMDR, but we expect to be able to forward a response to the NMDP within the next two weeks...It is our hope that an agreement, satisfactory to both organizations, can be ratified as quickly as possible." To my knowledge this agreement has not been ratified as yet, but some components of the AABMDR have joined the NMDP as donor centers.

A third issue is that of patient access to the NMDP registry which was repeatedly brought up during the hearings. I have to admit that I was not aware of this as an issue. We will address it promptly.

To conclude my comments about the role of the Institute in this matter, let me say that over the months since we have been responsible for the program, we have intervened quite often to resolve problems, but I must confess our effectiveness has not been consistently significant. Again, we believe that the constitution of an independent Policy Committee will greatly help resolve the remaining issues between AABMDR and NMDP, and assure that the Federally funded bone marrow transplantation program truly serves all the American people.

Clinical Studies

The second question was about the clinical studies/trials conducted under the auspices of the program. As previously said, I must agree that the progress has not been as great as could have been. As an explanation, I should say that we have been overwhelmed by the donor recruitment effort. In one year, we have entered about 50,000 names in the program and done approximately 230 transplantations. These activities have keep us very busy. Nonetheless, the following projects are underway or completed:

- Comparison of results of unrelated-donor marrow transplantation with those of related donor marrow transplantation. Survival, disease recurrence and complications are the end points of this study.
- Determination of what happens to patients for whom a preliminary donor search is initiated, but who do not receive a transplant. Of course, the reasons for patients to drop out of the formal search are many, but some may be related to policies and procedures that need to be changed.
- There is an observational study on the psychosocial aspects of marrow donations and the altruism of donors.
- The prevention of graft-versus-host disease by depleting the marrow of its T-cells prior to transplant is being assessed.

Currently, a number of major studies are under consideration. I am confident that as the management difficulties of the program settle down, and as more transplantations are being done, we will see the initiation of many of them. As I said during the hearings, this program gives us rich clinical material from which many research and clinical advances will be derived.

I hope the above comments address your questions. Please do not hesitate to contact me if I can provide additional information.

Sincerely yours,

C. Lenfant

Claude Lenfant, M.D.
Director

The CHAIRMAN. Senator Kassebaum?

Senator KASSEBAUM. First, I would just like to say that while there are tragic gaps, as we certainly heard from the previous panel, I do think that in the 4 years since it was created,the National Marrow Donor Program has been a program that has had an extraordinary impact. There are now almost 100,000 names in the registry, and there is a growing awareness of the importance of this program. It seems to me that it is one of the more unusual Federal programs or Federal initiatives and has, in a brief period of time, had some success. I don't think we want to lose sight of that.

Dr. Lenfant, I know in your testimony you say that the program consists of five parts. And I think it is important, without going through all five of those parts of the program, to have it very clearly understood in the record that there are many facets to this other than just the testing. Of course, that is first and foremost a very important part, and I am pleased to here you say that you believe that there should be more funds redirected within the program to testing at this point.

But what would you say in your evaluation of the program beyond the testing is the most costly and most important part of the entire program?

Dr. LENFANT. Well, I think, Senator, that I should say at the outset that it has been an extraordinarily successful program. It is a very complex program because, as you saw from the previous witnesses, people who get into it get in because of a personal crisis. And of course that makes dealing with these individuals and trying to solve the issues extremely difficult.

But at the same time that is the force which, in my opinion, has driven this program to the success that it has reached today. And if it wasn't for all the volunteers who have been behind this program, who have motivated its creation by Congress, we would not be today where we are.

The typing is an issue, but another significant issue, to me, is to deal with these crises as they emerge. As you know, there is a continuous flow of donors who are recruited, but every so often there is a situation which is picked up by the media for whatever reasons and immediately it amplifies the problems tremendously. And dealing with that situation makes it extremely difficult.

I think we have to be honest with ourselves. Today we are—previously we were talking about 100,000 potential donors in the registry—today we are talking about 250,000, and we will reach that number within one year or two years, whatever. We will reach it. I am very confident of that.

But what I think we all must keep on remembering and realizing is that even when we have 250,000 names in the registry, there will still be cases like in the Atlas family or the Johnson family. It will never be possible to have in a registry enough donors that will match all the possible genetic makeups that we have in the American population, or elsewhere for that matter.

So what we are going to do is to minimize the number of crises from perhaps one a month to one every three months or six months. But the problem will remain, and that, in my opinion, is going to be the most difficult thing for us all, we who administer

the program, the Congress who hear the American people and all the problems and try to help. We will always have that problem, and I think that that is really a real issue that we have to be aware of.

Senator KASSEBAUM. Thank you very much.

The CHAIRMAN. May I, Doctor, just ask one final area. That is, what is happening regarding the clinical trials associated with the bone marrow registry? What kinds of questions are being asked through this research, what kinds of problems are being looked at?

Dr. LENFANT. Well, permit me to say first, Senator, that the reason why the institute is so interested and so supportive of this program is that it gives us access to a very rich clinical material that is going to allow us to answer research questions which will do two things: It will make the technology much better, and it will allow us to expand the availability of that technique to many cases which today do not have the benefit of it.

We are talking about 200, 250 cases a year. I estimate that in fact in this country alone, there could be 6,000 or 7,000 individuals who could benefit from that technology. To reach to that number, we have to continue our research programs very actively.

One of the avenues, of course, that we are pursuing are clinical trials which will address some questions such as graft versus host disease, graft versus leukemia disease, and how we can best define the patients who will enter in this situation or that situation so that basically we can anticipate problems relative to the transplantation of bone marrow.

So we have now, now we are building up, if you want, a registry of cases, and once we have enough we will have enough cases in this registry—after all, we have only 290 cases in this country at this time—we will be able to start these clinical studies with the expected benefits which I just described a moment ago.

The CHAIRMAN. OK.

[The prepared statement of Dr. Lenfant follows:]

PREPARED STATEMENT OF CLAUDE LENFANT, M.D.

I am Dr. Claude Lenfant, Director of the National Heart, Lung, and Blood Institute (NHLBI), National Institutes of Health (NIH). I am pleased to appear before you today to offer testimony about the National Marrow Donor Program (NMDP), supported by an NHLBI contract to the American Red Cross.

The NMDP was established in July 1986 by a contract from the Office of Naval Research, Department of Defense (DOD), to the American Red Cross. The initial goal of the program to confirm that marrow transplantation from matched, unrelated donors was medically feasible has been achieved. Now the major goals of the NMDP are to provide HLA-matched marrow donors for those patients who need a transplant but lack a suitably matched relative and to serve as a focal point for bone marrow research. It was estimated that matched unrelated donors were required for between 60 and 70 percent of prospective marrow transplant candidates. However, that percentage may now be greater because of the decrease in average family size. In February 1989, with a Congressional mandate, the National Marrow Donor Program was transferred from the Department of Defense to the National Heart, Lung, and Blood Institute, National Institutes of Health, Department of Health and Human Services. The NHLBI is pleased to administer this program. Not only is it valuable for the American people, but it offers research potential consistent with the Institute's responsibilities relating to the nation's blood resource and to non-malignant blood diseases.

The program consists of five parts: 1) one coordinating center to establish and manage the registry of volunteer marrow donors; 2) more than 60 donor centers to recruit marrow donors and follow them through the

donation process; 3) marrow collection centers, many of which are also transplant centers, to harvest the marrow from matched donors for shipment to marrow transplant centers; 4) more than 30 marrow transplant centers to select patients who are medically suitable for unrelated-donor transplants and to perform the transplant; and 5) research activities to include psychosocial assessment of donor motivation, a repository of viably frozen cells from each donor-recipient pair as a resource for future research, and an assessment of program activities and results.

The first searches for HLA-matched donors were conducted in September 1987 and the first transplant was performed in December of that year. Now, less than four years after the contract was activated, the registry has enlisted nearly 100,000 volunteers, and participating transplant centers have performed more than 300 transplants from registry donors. The overall results of unrelated-donor marrow transplants, when patients with like diseases and like disease stages are compared, are similar to those of related-donor marrow transplants. Patients for whom a diligent search for a donor is made have a better than 30 percent chance of receiving a transplant. The activities and accomplishments of the program have been truly impressive.

How the Process Works

NMDP registry donor searches can be initiated only by participating marrow transplant centers and not by individual patients or their families. We think that this is best because it limits the chance of raising unwarranted hope in patients and their families when the disease process makes a transplant an inappropriate medical treatment. If the preliminary, no-fee search of the file produces one or more HLA-A and -B antigen matches

(and more than 90 percent of them now do), the transplant center may then request a full-fledged, or "formal," search. Based upon the experience of the requesting center, one or more of the A, B matching donors may be recalled for HLA-DR typing or, when appropriate, mixed-lymphocyte-culture crossmatching. Transplant centers take more donor characteristics into consideration than just the HLA type when determining which donors to pursue further. The formal search carries a small fee and, when potential donors are identified, there are additional costs to patients for further donor testing, such as HLA-DR and the mixed-lymphocyte-culture crossmatch procedure. It is extremely important to protect the donor's safety and confidentiality while obtaining informed consent and proceeding to the actual donation. It is the responsibility of the donor center, in consultation with the transplant center, to evaluate donors carefully by physical examination and laboratory tests to insure that they have no conditions that might needlessly reduce the chances of a successful transplantation or impose a risk of complications for the recipient. The NMDP coordinating center obtains follow-up information on donors and recipients to help improve our understanding of marrow transplantation.

All donors in the file are tissue-typed for the HLA-A and -B antigens. The $75 cost of the typing is covered by funds derived from a variety of sources, including NMDP, private sources, and charitable giving. In HLA-A and -B typing for marrow transplantation, splitting of the major types into subtypes is important. Not all laboratories are, or need to be, equipped to perform the subtype splits required for marrow transplantation. Failure to detect subtypes can result in false matches, leading to costly and time-consuming retesting. HLA-DR types are also very important in marrow

transplantation, but less than 30 percent of the donors are so typed. It is cost-effective to perform A, B, and DR testing together, but that would entail nearly twice the cost and severely tax available laboratory capacity. Nevertheless, it is very important to perform DR typing prospectively because it speeds the search process and permits transplants for patients before they become too ill to tolerate the procedure. In addition, large-scale patient-focused drives strain even the capacity for A and B testing. The Institute is working with the NMDP to redistribute funds to support HLA-A, -B, and -DR typing for both planned day-by-day recruiting and patient-oriented drives. In the contract year now drawing to a close, nearly $400,000 in contract funds, more than $3 million of charitable funds raised through the LifeSavers Foundation, and more than $100,000 of fee-for-service funds were directed to HLA typing.

Program Funding

Overall funding for the program comes from several sources: 1) Federal contract support of $3.671 million in the contract year ending April 30, 1990; 2) fees-for-services provided to marrow transplant centers, estimated to be at least $4.2 million for the same period; and 3) charitable gifts through the LifeSavers Foundation and other interested organizations, estimated to be more than $3.0 million. The services for which fees are charged include recalling donors for HLA-DR typing and mixed-lymphocyte-culture crossmatching, performing donor evaluations through physical examination and laboratory testing prior to actual donations, and providing for donation of the marrow and its transport to the transplant center. Most of the funds pass through the coordinating center to donor centers or collection centers. Any excess of income over expenses is being used to

expand the program, including the registry. Charitable funds are raised to assist specific patients and also to support the program as a whole. Most of the charitable money goes to support HLA-A and -B typing during patient-focused donor drives or to support HLA-DR typing for patients who find A and B matches in the registry.

Registry

The registry now contains nearly 100,000 volunteers. Although impressive gains have occurred within the past few months, the registry still contains too few representatives of American minority groups. Tissue (HLA) types are inherited and some combinations of A, B, and DR types are more common in some racial-ethnic groups than in others. While some combinations are typical of certain groups, the "melting pot" effect in the United States and throughout the world makes very few combinations exclusive to any one group. Increasing international cooperation among marrow registries is helping both the United States and other countries by expanding access to donors in other national groups. In addition, the NMDP and the Institute are now making every effort to ensure that the registry will be representative of the American people. At least six marrow donor centers have begun to recruit marrow donors from whole blood donor lists and are making special efforts to recruit minorities. Informational brochures targeted to minorities have been prepared. The program is planning to use focus groups to help determine how best to deliver the message of minority needs to appropriate groups. Finally, the NHLBI National Blood Resource Education Program (NBREP) is allocating additional resources to stimulate public awareness of the need for minorities to participate in the registry. The NBREP, initially devoted to lay and

professional education regarding blood transfusion, involves both professional and non-professional community groups. The additional resources permit the NBREP to expand and assist with marrow donor recruitment and to increase the participation of appropriate new community groups in the process. The results of an NBREP survey about minority blood donors will assist in this endeavor since recruiting marrow donors from among blood donors is effective.

Marrow donor recruitment employs three strategies: 1) planned solicitation from whole blood and specialty blood donor lists, community organizations, and local chapters or divisions of national groups; 2) individual recruitment through increased public awareness; and 3) patient-focused community, regional, and national marrow donor drives. With each of these strategies, it is important that donors be appropriately screened for suitability and that their consent to participate be based upon adequate information.

The NMDP has evolved considerably since its inception. Due to the cost of HLA typing, it was initially planned to recruit donors from individuals already HLA typed by blood centers for another purpose. However, the number of donors available from this source was overestimated and consequently the need for funds for HLA typing was unanticipated. When it was confirmed that unrelated-donor marrow transplants were medically feasible, the focus of the NMDP shifted toward providing donors and away from conducting research. A goal for the registry of 100,000 donors was believed to be adequate to provide most patients with donors. Unfortunately, this number was found to be too low, so the NMDP has adopted a new, but still preliminary, goal of 250,000. Reaching the new goal will

require that an additional 150,000 individuals be typed for HLA antigens. At a cost of $75 per person, the total cost to reach the new goal will be $11.25 million. If there are no new technological breakthroughs and if HLA-DR typing is to be performed as well, the figure will double to $23 million. To DR type those in the current file that have only HLA-A and -B typings would take an additional $8.9 million. Hence, to attain a registry of 250,000 donors, all typed for HLA-A, -B, and -DR, would require more than $31 million. Regardless of the figure, we expect the cost to be derived from a combination of public and private sources. As the 250,000 figure is approached, program performance in providing matched donors will be reassessed and the frequency of HLA combinations in different population groups will be recalculated. It is my opinion that the goal will again need to be raised and the distribution adjusted for the registry to serve the health needs of the nation. Nonetheless, it is important to understand that there will always be some patients with HLA combinations so rare that no matter what size the registry may be, a matching donor cannot be found. The original contract, administrated by the DOD, was intended to provide seed money, with the program becoming self-sufficient within three years. Because of the need for further research and development in the field of marrow transplantation and because of the high costs of HLA-typing associated with donor recruitment, it is likely that a continued Federal role will be necessary for the foreseeable future.

Oversight

The NMDP volunteer Board has played an important role in the inception and development of the program. The Board was originally organized as a subcommittee of the American Red Cross Blood Services Committee. We are

now looking at new managerial approaches. The Institute is working to qualify the National Marrow Donor Program, Incorporated, as a Federal contractor and effect a transfer. The NHLBI plans to appoint a policy committee to assist the Institute in working with this new organization toward further growth and development of the program.

Standards

The NMDP, through its Board and Standards Committee, has set standards for operating the many parts of the program. Some standards have been controversial and many have been modified as new information has become available. Marrow transplantation from unrelated donors is new and still evolving. The donation process is not innocuous, requiring general or spinal anesthesia and 1-2 quarts of marrow fluid to be withdrawn from the hip bones. The fluid and blood lost is replaced by previously donated autologous blood. Most donors leave the hospital after 1-3 days and resume normal, or nearly normal, activities soon thereafter. Although no NMDP donor has had a serious problem from the donation itself, a very small number of related donors have had serious, but not fatal or long-term, consequences. We believe that it is important to maintain this record of safety for the marrow donor program.

Marrow from another person, related or unrelated, may react against the recipient causing graft-vs-host disease, which can be severe and sometimes fatal. The recipients of marrow from unrelated donors have more severe graft-vs-host disease than do those from related donors. Accordingly, a higher degree of skill is needed for allogeneic (from another person) marrow transplantation than for autologous marrow transplantation; the highest degree of skill is needed for allogeneic transplants when the donor is not related to the recipient.

The need for transplant center standards has not been disputed, although some of the individual standards have been. The current NMDP Transplant Center Standards can be met by any center that has made a commitment to performing allogeneic transplants. Furthermore, the standards are similar to those recently endorsed by the Executive Committee of the American Society of Hematology and the Governing Board of the American Society of Clinical Oncology and published in the journal, Blood. Nevertheless, one of the duties of the NHLBI Policy Committee will be to advise the Institute on further development of the standards and changes recommended in them by the Standards Committee and the NMDP Board.

In addition to the NMDP, several smaller registries are federated into the American Association of Bone Marrow Donor Registries (also known as the American Registry or AR) and coordinated by the Caitlin Raymond Foundation, Worcester, Massachusetts. The registries of the AR were founded by individuals or families who sought unrelated marrow donors before a national program existed, and are largely staffed by volunteers whose viewpoint is similar to that of many members of the NMDP Board. The AR is strongly patient oriented. Virtually anyone can contact the AR coordinating center and begin a search for a marrow donor through AR affiliated registries and through some foreign ones. If a matching donor is found, patients and their physicians must seek a center to perform the transplant, and must themselves assess the center's qualifications to perform unrelated-donor transplants. As encouraged by the Congress, I have met with representatives of the AR and suggested that they work closely with the NMDP to try to resolve differences. I believe that things are improving and progressing satisfactorily. Recently, two of the registries that participated in the AR have joined the NMDP as donor centers. The

NHLBI Policy Committee is expected to help the Institute resolve any remaining differences between the NMDP and the AR and to achieve the goal of providing donors for patients in need.

Potential Research Avenues

Although the results of marrow transplantation are encouraging and many lives are being saved, much more needs to be done to understand and improve the scientific aspects of the process. Direct and rapid access to the very rich clinical and laboratory material from the NMDP provides an exciting stimulus to research in the basic biology of cell growth, development, and transplantation. For example, the Institute is about to announce a new research program to study the primitive source cells (stem cells) for all blood cells. The program will focus upon growing the cells in the laboratory and examining their growth and development as well as their response to newly discovered cell growth factors. The NHLBI is also exploring ways to support improvements in HLA typing so that it can be done more efficiently, more accurately, and less expensively. With better HLA typing, more can be learned about how close the matches must be. Although it is very unlikely that anything remotely resembling the "universal donor" (blood type O) of blood transfusion will be found, we believe that some mismatches are likely to be less troublesome than others. The marrow donor-recipient cell repository is an invaluable resource for this research. It is also expected to benefit solid organ transplantation and, thus, these activities will help make all transplantations more effective and less costly so that they can be made available to all Americans who need them. The NHLBI intramural program is starting a marrow transplant unit that will combine research on basic transplant biology with the gene therapy activities of the Institute.

The National Marrow Donor Program is undergoing an evolution in its management and organization. We believe that it should proceed in an orderly fashion, respecting appropriate rules, policies, and procedures to assure the safety and confidentiality of marrow donors and the best interests of marrow transplant recipients. The Institute will continue to administer the program in the interest of all Americans who might participate, and will use all sources of information, to help best chart its course.

Thank you for the opportunity to appear before you today. I will be pleased to answer any questions you might have.

The CHAIRMAN. Ms. Keller.

Ms. KELLER. I am Joan Keller. I am president of the American Bone Marrow Donor Registry. With me is Joann Raymond, who is the director of the Caitlin Raymond International Registry and secretary of the American Registry. I would like to thank you and the committee for the opportunity to be here.

I would like to give you just a brief background on the American Registry today, since maybe some people are not familiar with it.

The American Bone Marrow Donor Registry originated in Louisiana in 1984, when over 400 people responded to an appeal by a local child who needed a bone marrow transplant or a bone marrow donor. It quickly became obvious to those who were helping with that effort that there was an even greater need out there when parents and relatives from all over the country started calling to ask us to search our little file.

We made over 100 phone calls to transplant centers such as Wisconsin, Seattle, Iowa, etc., the Leukemia Society, hematologists, oncologists, and parents and relatives who had gone through the agonizing problem of trying to search, unsuccessfully, for their own relatives. And we made a decision that we had to continue what we were doing, and the Louisiana registry was incorporated as a tax-exempt nonprofit corporation, formed a board of directors, and got an excellent medical advisory board to work closely with us.

Other regional registries were similarly developed as time went on, mostly by family members of patients who had also recognized the need for a bone marrow donor source. And they were helped to establish, as we were, and then ultimately the incorporation of the American Bone Marrow Donor Registry united these efforts, and standards and procedures of operation were adopted, and a trifold function and purpose were identified.

Those were: first, to develop and maintain an ever-increasing source of marrow donors; second, to coordinate and process search requests as efficiently and cost effectively as possible; and third, to provide both donor and patient advocacy.

The regional donor centers are responsible for donor recruitment, donor file maintenance within defined geographic areas, totally covering the entire country, and to quickly and efficiently conducting searches of their files.

The growth of the donor panel has been consistent, with an emphasis placed on donor education and donor support. Provisions for protection of privacy and absolute confidentiality of the donor are paramount, as are concerns for careful counseling, medical evaluation, harvesting, and insurance coverage for each donor.

To date, the costs associated with donor recruitment have been borne, in many cases, by the donors themselves, by sponsoring corporations or organizations, by fundraising efforts on the part of patients' families, and by fundraising efforts on the part of the regional donor centers themselves.

The Caitlin Raymond International Registry is the American Registry bone marrow donor coordinating center for patient services. Through this division, patients, physicians, and/or transplant centers are provided with one-call, worldwide access to donor sources. The American Registry accesses all donor sources immediately for a one-time search initiation fee. Only three of the nine

U.S. registries charge additional access fees, two in Israel, one in Belgium.

The attending physician and patient at the start of the search process are sent completed request forms with instructions on how to initiate searches in those three registries with additional fees, along with instructions for accessing the National Marrow Donor Program.

International cooperation has been and continues to be extremely gratifying. The Soviet contingent was over here just a couple of weeks ago to meet with us, and we have had a tremendous working relationship with most of the European countries and also some of the Asian countries.

Through a grant provided by U.S. Sprint, the American Registry donor centers and some of the foreign donor sources are connected by electronic communication, which has shortened response time considerably. There are other foreign registries who are going to be connected very shortly. Hadassah went on line just the other day.

The American Bone Marrow Donor Registry which was begun by volunteer effort is today composed of a fully staffed patient search division supported by search fees, and regional donor registries which are run by a combination of dedicated volunteers and some paid staff.

There are some concerns in spite of the tremendous progress which has been made in the transplant field and in the area of donor recruitment. There are some concerns which I would like to identify and discuss to some extent today.

Our first and primary concern is that the immediate and routine disclosure of all donor sources to all patients and physicians is critical to the successful outcome of the search process, for many patients. A registry which does not inform the patient or physician of the existence of another registry within this country not directly affiliated with its program or a registry which performs searches in time-delayed incremental stages may delay the identification of an acceptable donor, and that delay may sometimes result in the death of the patient.

We had a comment here this morning, and we verified as Congressman Young left, the three patients whom he has committed for himself to make sure he can do everything in his power to identify a donor for, have not been informed of the American Registry and have not been submitted for search to the American Registry. He is being sent the forms immediately. But those patients have so far been denied access to about 150,000 donors.

The CHAIRMAN. I don't understand. We heard from Dr. Lenfant that these negotiations are going ahead, that this is moving forward.

What about it, then, Dr. Lenfant?

Ms. KELLER. Well, I don't know the story with Congressman Young, but he did verify the fact that those patients did not know of the American Registry and their searches have not been submitted to the American Registry. They will be, I am sure, within the next week or so. But I don't know how long those patients have been searching. However long it is, they have that much of a delay that they have searched.

The CHAIRMAN. Well, I think we all are not going to tolerate bureaucracy on it. We are just not going to do it. I just want to make that very clear. I mean we hear that conversations are going on, the other ones aren't getting it. And we are just not going to tolerate it, and we are going to name organizations and name names and tell who is not pulling their share of the weight. I want to make it very, very explicitly clear.

So we are hopeful that this can be done in a way that any sensible, logical, rational groups would try and do it. But I think all of us have been around here long enough that we can say that that doesn't always happen. But here is one area we are just not going to do it. And I think you have got that sense from all sides that have spoken today. And we want to work with you in ways to make it easier to do that, and we commit ourselves to that. And you have got to help us if there is some way that we can be a constructive force.

But we are not going to be in a situation after this process moves through in terms of the authorization—I don't even think it has too be that; it just seems to me that you ought to be able to work that out immediately—we are just not going to tolerate that. And I cannot stress enough or emphasize it enough.

Why don't you continue.

Ms. KELLER. I will go off the beaten track one more time. There is a child in a southern State right now who learned of the American Registry through a TV program, the grandmother did, and got in touch with us. The search was initiated through the transplant center, and the child will have a transplant within the next two weeks, because almost immediately we identified a donor who was previously ABDR type, first and level match, and the MLC is proceeding at this time. And that child will be transplanted.

That child could have had access to that donor a year and a half ago.

The solution right now is the registries should routinely, both of us, both American national registries, should routinely and immediately provide patients and physicians with written notification of all donor sources. A registry which ignores the existence of other resources fosters an atmosphere of competition, and this is an area in which competitive attitudes cannot exist.

The fee structures are another concern of ours. The fee structures directly related to the search process within a registry needs some form of control or should possibly be governed by the registry itself. A registry which has no control over wide variances in surcharges or administrative fees added to its own search fee structure, which may be extremely fair by individual transplant centers, results in discontinued patient searches.

A patient who is unable to afford access or administrative charges at one center is not always aware that access fees and administrative charges at another center may be well within his means or well within the amount that his own insurance company would be willing to cover.

This situation also pertains to DR typing second-level typing. The variance in charges may prove costly to a patient in terms of successful outcome. A patient, for instance, who has about $5,000 worth of coverage to DR type or do second-level testing may not be

aware that going through one center that amount of money will type 11 donors, where going through another center that same amount of money would have been enough to cover 17 typings.

The American Registry accepts search requests from the attending physician and/or transplant center and allows the same to request DR typing. The fees for search and DR typing are standard and the fee schedule is disclosed at the beginning of the search.

A solution to the overall problem might be that a uniform fee structure should be implemented in either or both registries. If access to a program can be made only through approved transplant centers or through approved centers, the center's approval could possibly at least depend, in part, on their acceptance of the fee schedule. At the very least, the registry should provide patients and physicians with a list of individual center's fees at the beginning of the search process.

The third concern is disclosure of protocols and criteria at transplant centers as they relate to treatment of various diseases, disease status, patient age, etc., is essential to efficient donor searches. Requiring that activation of a donor search be done only through participating transplant centers which have specific criteria for acceptance of a patient may sometimes result in unnecessary elimination of patients from the search process. If a patient's disease status changes during the search process, that center may terminate the search and that patient may not be informed that he or she might still qualify for donor search at another transplant center.

Similarly, centers have different criteria for degree of acceptable donor match. A donor search which results in the identification of donors who do not meet the criteria of the access center might have been acceptable at another center. One center might accept only because of the patient's disease, age, etc., only perfectly matched donors, where another center may have a protocol which allows for a minor mismatch to be acceptable and have the statistics to show that they have a success rate to bear that out.

Sometimes the patient is not advised of the alternatives or the donors identified, terminates the search and is not aware that they could have continued the search through another center. Perhaps the solution is to push back the time that is required to choose transplant center until the search process has allowed the determination of the best donor available to a particular patient. Whether the patient is going to be able, from indications of search results, to find a perfectly matched donor or a donor that may be the best that could be found with a minor mismatch.

We need to make available to the patient and physician information regarding criteria at all transplant centers under consideration for a particular patient, including degree of acceptable donor match, diseases, disease status treated under their protocol, age acceptance, etc..

We believe that patient advocacy needs to be and is an integral part of the search process. A registry which focuses on the needs of the transplant center and places little emphasis on the needs of the patient may ultimately fail the patient, and that is the very reason for which the registry was established.

Unrelated donor searches often need to be tailored to meet the circumstances of individual patients. The patients' HLA typing, disease status, financial situation, etc., sometimes necessitate a change in the normal search procedure to adequately explore all search options.

The American Registry currently assists patients and physicians in accessing and understanding resources available through all existing registries. Assistance is also provided with referrals to transplant centers appropriate to the patient's age, disease status, degree of match, etc. The coordination centers are not only responsible for search and follow-up procedures but serve as information centers where ongoing individualized support is available.

Long-term solutions should be that a registry must provide individualized patient assistance when necessary. The patient division should be a separate entity whose focus is solely patient-oriented. It has been our experience that no one office or one particular person or function within the American Registry can simultaneously handle advocacy for the donor, the transplant center, and the patient. The duties are separate and probably should be handled by separate divisions.

According to the big point we talked about today, a steady increase in the donor pool must be maintained, with particular attention being given to the quality of the donors being recruited and commitment to the program. The recruitment of well-informed, medically acceptable, properly motivated, truly committed marrow donors can be attained only through well-organized, controlled testing drives. Massive donor testing resulting from sensational emotional appeal brings numbers but not necessarily good, viable donors.

Donor drives must involve interaction by the registry with the sponsoring entity, whether it be the patient's family, organization, or corporation. Laboratory representatives must also be well-versed on the recruitment effort and donor qualifications. And then personal contact with donors throughout the stages of testing must be maintained.

I don't mean to sound negative. I don't mean to say that efforts like the families we have mentioned here today are wrong. They are not. But while those families or while people have massive publicity, they need to be working very closely with information readily available to predistribute to donors or to make sure that when there are donors being tested where there is over 500 at a particular drive, that there are enough people on hand, medical personnel, enough people trained to properly screen the donors, to make sure that the family that is raising money is paying for viable donors who are coming in to the system, that the donors themselves understand what this process is that they are volunteering for.

We took over a drive very suddenly that needed to be continued. People were already scheduled, etc., at a church, and we did step in and were able to finish a drive. The drive was not one that we had personally set up and worked with the donors prior to. Out of that, maybe 400 or 500 to 600 people who were tested that day, there were about 40 who should never have had the blood drawn and had to be eliminated. There were others who really were not aware of what was going on.

We have conducted large drives but we have made sure that prior to the drive the information has been disseminated to donors, that the day of the drive that they have not read the information, they cannot be drawn, they cannot have blood drawn until they have read all the information that is there and they have been properly screened.

In order to sustain the continued growth of the donor pool, some funding will be essential. To date, the American Bone Marrow Donor Registry has used no public money and has amassed a donor file of about 30,000 donors at a cost of $60 per donor. The total cost to date or moneys raised have been approximately $1,600,000.

The CHAIRMAN. I will give you just another minute or two because I want to get Dr. Graves' testimony, and then I will question both of you. So we will put your full statement in. But would you like to wind up?

Ms. KELLER. I'm sorry. Me?

The CHAIRMAN. Yes.

Ms. KELLER. The other big concern, one other that I would like to make is that accessibility to marrow transplant must be made more equitable who, for those financial considerations, may be denied. There are 35 million people uninsured in the United States, an equal number are uninsured, and because of the system of restricting donors to being used only in certain transplant centers, there are many, many Americans being left out of the chance not only to have a marrow transplant but to be even searched.

In Louisiana alone, there are 30-plus Medicaid patients whose coverage will not, if they leave the State for transplant, are not eligible for transplant, and they have not even accessed the National Marrow Donor Program because the search itself would be futile.

One short point is that we believe there should be criteria with regard to transplant centers. We believe the criteria should be looked at without prejudice, should be equitable to allow patients access to transplants. Perhaps the criteria should be established by a Federal agency or review should be in the province of an outside objective agency and not an entity that in essence is part of the program.

I think the American Bone Marrow Donor Registry was begun by volunteers with a deep empathy with patients, but it has matured into a major entity in the world of marrow transplant. It has demonstrated the ability to generate viable, well-informed marrow donors, establish worldwide cooperation, etc.. I think to date there are two national registries that function in this country with perhaps different perspectives and goals, but the time has come when the experiences of both should provide a base on which to improve the search process for all involved. The areas where each has demonstrated expertise should be fostered, recognizing and enlisting the individual skills of existing organizations under the auspices of the NIH, should increase the efficacy and decrease the cost of this program. And it is essential to the success of the program that these organizations begin to work together.

Thank you.

[The prepared statement of Ms. Keller follows:]

PREPARED STATEMENT OF JOAN A. KELLER

The American Bone Marrow Donor Registry originated in Louisiana in 1984 when over 400 people were HLA typed in response to an appeal for a local child who was in need of a bone marrow donor. It quickly became obvious that an even greater need existed and after over 100 phone calls to transplant centers such as Wisconsin, Seattle, Iowa, to individual hematologists/oncologists, to parents and relatives who had gone through the nightmare and emotional stress of trying unsuccessfully to locate a marrow donor the Louisiana HLA Registry was incorporated as a tax-exempt, non-profit organization with an established board of directors and medical advisory board. Other regional donor registries were similarly established by family members of patients who from personal experience recognized the need for a marrow donor resource. With the incorporation of the American Bone Marrow Donor Registry these efforts were unified and standards and procedures of operation were adopted. A trifold function and purpose were identified:

1. to develop and maintain an ever-increasing source of marrow donors
2. to coordinate and process search requests as efficiently and cost effectively as possible
3. to provide both donor and patient advocacy

The regional donor centers are responsible for donor recruitment and donor file maintenance within defined geographic areas, totally covering the entire country and for quickly and efficiently conducting searches of their files. The growth of the donor panel has been consistent with an emphasis placed on donor education and support. Provisions for protection of privacy and absolute confidentiality are paramount, as are concerns for careful counselling, medical evaluation, harvesting, and insurance coverage for the donor. To date the costs associated with donor recruitment have been borne in many cases by the donors themselves, by sponsoring corporations or organizations, or by fundraising efforts on the part of patients' families.

The Caitlin Raymond International Registry is the American Bone Marrow Donor Registry's coordinating center for patient services. Through this division patients' physicians and/or transplant centers are provided with "one call" worldwide access to donor sources. The American Registry accesses all donor sources immediately for a one-time search initiation fee. Only three of the non-U.S. registries charge access fees (two in Israel, one in Belgium). The attending physician and patient, at the start of the search process, are provided with instructions and completed search request forms to intiate searches in these three, as well as instructions for accessing the National Marrow Donor Program. International cooperation has been and continues to be extremely gratifying. Through a grant provided by U.S. Sprint, the American Registry donor centers and some of the foreign donor sources are connected by electronic communication which has shortened response time considerably.

The American Bone Marrow Donor Registry, which was begun by volunteer effort,

is today composed of a fully staffed patient search division supported by search fees, and regional donor registries which are run by a combination of dedicated volunteers and some paid staff.

In spite of the tremendous progress which has been made in the field of marrow transplantation with unrelated donors and sources of unrelated donors, there are some immediate areas of concern which must be identified and discussed at this point:

1. Immediate and routine disclosure of all donor sources to all patients and physicians is critical to the successful outcome of the search process for many patients.

A registry which does not inform the patient/physician of the existence of the American Registry or other donor sources not directly affiliated with its program or which performs searches in incremental stages may delay the identification of an acceptable donor (a delay that sometimes results in the death of the patient.)

Solution: Registries should routinely and immediately provide patients/physicians with written notification of all donor sources. A registry which ignores the existence of other resources fosters an atmosphere of competition in an area in which competitive attitudes can and do cost lives.

2. The fee structure directly related to the search process within a registry should be governed by the registry itself.

A registry which has no control over wide variances in surcharges or administrative fees added to its search fee structure by transplant centers results in discontinued patient searches. A patient unable to afford access or administrative charges at one center is not always informed that fees may be considerably lower at another center and may not pursue his/her search. This situation when it pertains also to DR typing (second level donor testing) may prove costly to a patient in terms of successful outcome. A patient who has $5,000.00 worth of coverage for DR typing may not be aware that this amount will pay for typing 11 donors at one center but would have paid for typing 17 donors through another center.

The American Registry accepts search requests from the attending physician and/or transplant center and allows the same to request DR typing. The fees for search and DR typing are standard and the fee schedule is disclosed at the beginning of the search. Only when an HLA A,B,DR (first and second level) match is identified must the patient/physician choose a transplant center. The MLC (third level test) must be ordered by and performed by the transplant center.

Solution: Uniform fee structure should be implemented. If access to a program can be made only through approved centers, the centers' approval should depend, in part, on their acceptance of the fee schedule. At the very least, the registry should provide patients and physicians with a list of individual centers' fees at the beginning of the search process.

3. Disclosure of protocols and criteria at transplant centers as they relate

to treatment of various diseases, disease status, patient age, etc. is essential to efficient donor searches.

Requiring that activation of a donor search be done only through participating transplant centers which have specific criteria for acceptance of a patient may sometimes result in the unecessary elimination of patients from the search process. If a patient's disease status changes during the search process, that center may terminate the search without informing the patient that he/she may still qualify for donor search at another tranplant center.

Similarly, centers may have different criteria for degree of acceptable donor match. A donor search which results in the identification of donors who do not meet the criteria of the accessed center may result in the termination of the search process, when those same donors might have been acceptable at another center. Even those patients with the resources to arrange a second evaluation at another transplant center and a disease process allowing for the additional time involved, may not be advised of the alternatives or of the donors identified.

Solution: Postpone the time required time to choose a transplant center until the search process has allowed the determination of the best donor available to a particular patient; e.g. a perfectly matched donor, or a donor with a minor mismatch. Make available to the patient/physician information regarding criteria at all transplant centers under consideration, including degree of acceptable donor match, diseases and disease status treated under their protocol, age acceptance, etc.

4. Patient advocacy is an integral part of the search process.

A registry which focuses on the needs of the transplant centers and places little emphasis on the needs of the patient ultimately fails the patient and the very reason for which it was established. Unrelated donor searches often need to be tailored to meet the circumstances of individual patients. The patient's HLA typing, disease status and financial situation sometimes necessitate a change in the normal search procedure to adequately explore all search options.

The American Registry currently assists patients and physicians in accessing and understanding resources available through all existing registries. Assistance is also provided with referrals to transplant centers appropriate to the patient's age, disease status, degree of match, etc. The coordinaton centers are not only responsible for search and follow-up procedures, but serve as information centers where ongoing, individualized support is available.

Solution: A registry must provide individualized patient assistance when necessary -- the patient division should be a separate entity whose focus is solely patient oriented. (It has been the experience of the American Registry that is is impossible to simultaneously advocate for the donor, the transplant center and the patient. These duties are separate in the American Registry.)

5. A steady increase in the donor pool must be maintained with

particular attention being given to the quality of donor recruited, and committment to the program.

The recruitment of well-informed, medically acceptable, properly motivated, truly committed marrow donors can be attained only through well organized, controlled donor testing drives. Massive donor testing resulting from sensational emotional appeal brings numbers but not necessarily good viable donors. Donor drives must involve interaction by the registry with the sponsoring entity, whether it be a patient's family, organization or corporation. Laboratory representatives must also be well versed on the recruitment effort and donor qualifications. Personal contact with donors throughout the stages of testing must be maintained.

In order to sustain the continued growth of the donor pool, some funding will be essential. To date, the American Bone Marrow Donor Registry has used no public money and has amassed a donor file of 27,000 donors. At a cost of $60.00 per donor, the total cost to date is approximately $1,620,000.00. The Registry is at the present time processing approximately 10,000 requests for donor information. The increased awareness of the need for marrow donors is already resulting in a tremendous response from the population. Only about 1/3 of those responding, however, are able to pay the cost of testing. Also, indiviual patients' families are becoming involved with donor testing and putting forth tremendous effort to raise funds for donor typing. This should not be. The families have enough to deal with emotionally without the added pressure of fund-raising. The American Registry as have other registries recognize the necessity of appealing to the government for financial support of this effort. This does not mean that private contributions should not still be sought.

6. Accessibility to marrow transplant must be made more equitable to those who for financial considerations may be denied the chance even to search for a donor.

There are 35,000,000 people uninsured in the United States today and an equal number underinsured. Their only access to medical care is through their state Medicaid program..and many of these states have no program to fund marrow transplants which must be done out-of-state. A registry system which restricts donor participation to patients being treated in certain transplant centers denies many patients the chance for life which those donors are willing to give. Such a system also denies the donor the opportunity to give his/her own informed consent to donate to a particular patient.

The American Registry donors are accessible to all patients and the American Registry has worked with physicians whose patients could not have had a tranplant if the American Registry were not in existence. At the present time there are 30+ Medicaid patients in Louisiana alone in need of marrow transplantation. If the only donor these patients can locate is in a registry which restricts the use of the donors, these patients will not have a transplant. In fact, these patients have not even accessed any other registry in this country because they are aware of the futility.

Donors, themselves, are becoming aware of the limitations placed on their willingness to donate and several requests are received daily to have

records transferred to the American Registry. The original consent forms signed by the donors do not indicate that such restrictions will apply.

Solution: Donors, at the time they are tested by a registry which restricts participation, should be informed of that fact. Donors could possibly be given the opportunity to state on their consent form that they are willing to donate without restriction to certain tranplant center patients.

Priority, however, should be given to solving the underlying problem...how to give the chance of life to those who are denied because of financial circumstances.

7. Criteria with regard to transplant centers should be set and mandated. The question is, "by whom and how".

Criteria for transplant centers should be looked at without prejudice and should be equitable to allow patients to obtain transplants. Perhaps the guidelines of transplant center criteria should be established by a federal agency. Perhaps criteria review should be in the province of an outside, objective agency, and not an entity which is in essence part of the program.

SUMMARY

The American Bone Marrow Donor Registry which was begun by a dedicated group of volunteers with a deep empathy with patients has matured into a major entity in the world of bone marrow transplant. It has demonstrated the ability to generate viable, well informed marrow donors, establish world wide cooperation for reciprocal search capabilites, coordinate and process patient searches requests rapidly and efficiently, minimize the costs of the search process, and provide advocacy to both patients and donors. The accomplishments of the American Bone Marrow Donor Registry have been attained with private support, however, the point has been reached where, in order to maintain the level of efficiency, and be prepared for the increased activity in the transplant area funding will become a priority.

To date two national registries have functioned in this country with different perspectives and goals. The time has come when the experiences of both should provide a base on which to improve the search process for all involved. The areas where each has demonstrated expertise should be fostered. Recognizing and enlisting the individual skills of existing organizations under the auspices of N.I.H. should increase the efficacy and decrease the costs of this program. It is essential to the success of the program that these organizations begin to work together.

Respectfully submitted,

Joan A. Keller M.T. A.S.C.P.
President
The American Bone Marrow Donor Registry

The CHAIRMAN. Dr. Graves, I know Senator Durenberger, as a member of the committee, was very interested in trying to get by to extend a warm welcome to you. We are delighted to do that in his behalf.

Dr. GRAVES. Thank you. Thank you, Senator Kennedy, fellow board member Senator Kassebaum. I extend greetings to you from the admiral, who would have been here if he had not had a previous engagement in Chicago attending the board meeting of Navistar today. He asked me to call him immediately after the hearing and interrupt him as to the process as we went through it.

I have also with me Dr. Pat Beatty, who is the director of the Unrelated Marrow Donor Program and the Marrow Transplant Program both—he wears two hats—from Seattle. Seattle, as you know, the Fred Hutchinson Cancer Research Center has been the leader in the field of marrow transplantation since the first one was done by Dr. Goode at the University of Minnesota. Dr. Beatty told me this morning that the Fred Hutchinson Cancer Research Center had done 170 unrelated marrow transplants at this point in time.

I could very well have been sitting with the Atlas family. I have nothing but encouragement for the American Registry. My own daughter, in 1979, became the first recipient of an unrelated marrow. I, unlike the Atlases, did not have to search for a donor. This transplant occurred because a donor was a lab technician within the Fred Hutchinson Cancer Research Center.

What I did have to face, though, and probably what has begun the National Marrow Donor Program, was facing what was perceived to be a lack of attention to Laura's donor. This prompted the actual incorporation of the Laura Graves Foundation to promote donor advocacy. Our program is only as strong as our donors. Our program is only as strong as we protect our donors. And I am not talking about confidentiality, because that is number one. Number two is physical and moral support. Many donors don't need it, many donors do.

The basic principles of the National Marrow Donor Program are set down so that we first work for the patient. The minute a patient is enrolled in a transplant center, we do not worry about the patient any longer. We have excellent medical care in this country. We then worry about the donor, and we wish the donor to be handled and treated correctly.

I can't add much to the testimony that is ahead of me. You have my written testimony. I am more than happy to answer any questions that you might have.

[The prepared statement of Dr. Graves with attachments follows:]

PREPARED STATEMENT OF ROBERT C. GRAVES

Mr. Chairman and Members of the Committee, I am Robert Graves, veterinarian and Colorado rancher. While I was invited here today because I am the founding chairman and current Vice Chairman of the Board of the National Marrow Donor Program (NMDP) *[Attachment 1]*, I could just as well have taken my seat with the families. The urgency, the despair and the frustration that a family experiences when they are asked to wait is my experience as well.

On September 4, 1979, my daughter Laura became the first acute leukemia patient in the world to receive an unrelated marrow transplant with sustained engraftment. The transplant was extremely successful and a new era in medicine was launched. Laura later died of a relapse of her leukemia because of incomplete eradication of mature leukemia cells pre-transplant but, in many ways, it is because of her that we are all here today. She symbolizes the hope that has become real for three hundred and twenty families already and many, many more in the future. It is also because of the experience of Laura's donor that the National Marrow Donor Program was shaped. The lack of medical and psychological care post donation for Laura's donor made it clear to me and others involved that no matter how sophisticated a transplant center may be, additional resources are necessary to deal with the special circumstances of an unrelated donor. Hence, the establishment of the Laura Graves Foundation to serve as the donor advocate for unrelated donors to assure that they are treated appropriately, provided life and disability insurance, advance payment for donor care and offer counseling. The Laura Graves Foundation became the charitable arm of the NMDP last year.

Ours is a story of help and hope which we are addressing today. I have devoted my life, for the past decade, to helping blaze the trail toward a system that works, that's responsive to patients and protective of donors -- the strangers willing to give the living gift of life.

There are many, many others-- across the world -- who have also helped in this effort -- not least of which are the almost 100,000 volunteers on the National Marrow Donor Program's Registry. *[Attachment II]*

It is appropriate for us to look back over the trail of the past 20 years:

•Our longest living recipient with a related donor is almost 20 years post transplant; Our longest living recipient with an unrelated donor is seven years post transplant.

•In 1982, the first transplant center affiliation with blood banks utilizing previously typed platelet blood donors was signed between Seattle's Fred Hutchinson Cancer Research Center and Puget Sound Blood Center, the Portland Red Cross, Milwaukee's Blood Center of SE Wisconsin and the Laura Graves Foundation. This arrangement lagged because of a lack of patients and virtually no donors.

•Federal funding became the catalyst that allowed the beginning of the National Marrow Donor Program. Through an act of Congress in 1986, special and visionary guidance of the Navy, and now under the umbrella of the National Heart Lung and Blood Institute, ably directed by Dr. Claude Lenfant, a model program called the National Marrow Donor Program has been established. It has been lauded worldwide as **an excellent model for transplantation coordination** and is an excellent example of public-private sector cooperation.

Early donor recruitment continued to focus on HLA-typed platelet blood donors. After two years, it became apparent that this pool would never be of sufficient size to be very effective, nor was there any racial diversity of the file. In the summer of 1989, the NMDP Board acted to formally enter into community donor recruitment, focusing on patients that need a donor. Since that time, our recruitment momentum has been phenomenal and I do not see any loss in that momentum for the rest of this year.

•Our pool of medical knowledge is large enough now that we can definitely say that **unrelated marrow transplants are a viable medical therapy**. Not only is the transplant a cure when successful but new information also shows it to be just as or more cost effective than traditional therapy for some types of leukemia. For others, with aplastic anemia and other blood diseases, including some forms of leukemia, it is the only therapy.

• We still don't know how big the Registry must be to assure that most patients can find a match; unfortunately, some patients have such a rare combination of antigens that we may never find an unrelated match for them. What we do know -- and what is truly unique and inspiring -- is that Americans have responded by the tens of thousands. Please, focus for a moment on the phenomena: When we first started talking about a national registry, there was great skepticism that we could even build a registry of 50,000 volunteers. When we set our goal of 100,000 volunteers, we were scoffed at as being unrealistic. "Certainly, Americans would not be willing to go through the discomfort of donating marrow for a stranger," said our skeptics.

We now have a **goal of 250,000 U.S. volunteers, one million worldwide** and we're going to make it -- not fast enough for some patients unfortunately, but the hope remains because of the help we've received from all those supposedly uncaring Americans out there. Not only do we have close to 100,000 volunteers on our Registry but millions of dollars have been raised from the private sector to pay for HLA typing tests.

Think about that. We as a nation can be very proud.

•Our story of hope and help has another angle as well: Part of the National Marrow Donor Program's mission is research. Along with the many medical studies which are pooling significant information regarding transplants and donor experiences, we have established a stem cell repository. Blood samples are taken from every donor and recipient pair. Cell lines are now being prepared for study by the International Histocompatibility Workshop. The **insights scientists receive from their studies of these samples will, hopefully, lead to better understanding,** and yes, maybe a cure for blood diseases -- a cure which could someday eliminate the need for the vigorous therapy of marrow transplantation.

While research is an important component, **our primary mission remains to serve the patient while protecting the donor.**

•Three years ago, without the National Marrow Donor Program, only 25 unrelated matches were made each year. Today, approximately **25 miracle matches are made each month.** We hope that one day soon we will be finding that miracle match for 25 people per day *[Attachment III]*.

•Challenges remain in recruiting and protecting the prospective donor. Our program is set up to assure that the transplant center and patients do not have access to donor identification. Our experience has proven this system to be critical to the protection of the prospective donor. As we continue to expand our donor and transplant center network, our standards become even more essential to assuring a **quality system that runs smoothly for the patient while assuring the integrity of our volunteer registry** *[Attachments IV and V].*

It is important that we recognize the great sacrifice and contribution made by hundreds of families to help us recruit more donors and offer a true hope where two years ago, there was none. The Atlas family and the Joanne Johnson family of Maryland, the Chris Eiler family and the Judie Davis family of California all must be commended for their efforts to not only help loved ones but to help others in similar circumstances.

Also, a **desperate need for recruiting minority volunteers remains.** With all certainty, I can tell you that our **major roadblock is finding the funds** to pay for the typing test, not in finding volunteers. Six months ago, when our Registry had 40,000 volunteers, less that two percent were from any minority group. Today, we've expanded that to eight percent. While we're proud of our efforts, 2,900 African Americans or 2,500 Asian American volunteers is not enough to offer equal hope and help to our minority patients.

•We are hopeful that our **international expansion will add some of the ethnic diversity** we so desperately need. Please refer to *Attachment VI* which outlines our progress internationally. It has been stunning to see the political and cultural barriers dissolve as we discuss this Program and the need for international cooperation. I personally have been most intimately involved with discussions with Japan and the Soviet Union. Other than England, France and Canada, most countries are six months to two years behind us. We do not anticipate reaching our one million global goal until 1995.

Since Thanksgiving, well over one thousand news stories have discussed this Program. We have our January newsclips with us if you wish to review some of them. **When talking with reporters, we have said our Program needs three things:**

The first is Volunteers, especially from minority groups, to build the U.S. registry;

The second is Funds to pay for the sophisticated typing test which is done on two tablespoons of blood;

The third is Time to build the registry worldwide. This is time that families searching today do not have.

That has been our simplified answer. While avoiding some of the medical treatment challenges still confronting transplanters, I wish to give you an overview of our goals for the next 12 months:

1. Automation of Volunteer Donor Processing
We will automate our volunteer donor processing *[Attachment VII]*. With the help of computer technology, our Board has approved a system whereby the HLA typing of volunteer donors will be entered into our main Registry within a week of receiving the lab report. Since Thanksgiving, our rapidly expanding system has been strained.

2. Minority Recruitment
In the next month, we will implement an aggressive planning project regarding minority recruitment *[Attachment IX]*. We have targeted six minority groups: African Americans, Asian Americans, Hispanics, Native Americans, Middle Eastern Americans and Americans from the Indian Subcontinent. We will begin with African, Asian and Hispanic Americans. After extensive focus groups in four major U.S. cities for each group, a task force will review the results and conduct an open forum for even more input before making recommendations on how to more aggressively recruit volunteers from these minority groups. We will then conduct a similar effort with the second group of three minorities. We are seeking advice and participation by interested members of Congress in this effort.

3. Corporate Response Program Undertaken
Donor recruitment, because of attrition, will be a continuing challenge. While the majority of our volunteers have been recruited through family and community drives, we hope to evolve into a more consistent, institutionalized recruitment mode. This requires the help of employers

throughout our country. Our fledgling corporate response program shows great promise. Major corporations such as General Mills and McDonnell Douglas have responded to our plea and will be conducting employee recruitment pilot projects and paying for the typing test of their employees. Dozens of smaller companies have or are planning similar efforts. We must take the brutal burden of recruitment from families. This seems to be one logical route to take. As with our recruitment efforts in general, it is the funding that has been our wall when approaching these corporations.

We've also begun to involve the states in our corporate response effort. State model legislation is being considered by about two dozen states. It calls for paid leave for employees who become donors, paying for the typing test for the first 200 state employees who volunteer for our Program -- as we are asking private corporations to do -- and assistance from the state Commissioner of Health in educating state residents -- especially minorities -- about marrow donation *[Attachment VIII]*.

4. Continued Negotiation and Proposed Exchange of Preliminary Searches with Private Registries

A very special donor center and recruitment group of the National Marrow Donor Program is Heart of America, at one time the largest of the private registries. Now with 14, 000 donors, Heart of America serves a very special role for us, enrolling volunteers in remote regions and assisting families who wish to conduct recruitment drives. I must pause here to emphasize what a truly special role Heart of America has served for us in the year since joining the National Marrow Donor Program. I'm proud to announce that the next largest private registry, the New Jersey HLA Registry, also elected recently to join the National Marrow Donor Program as a participating donor center and recruitment arm.

Discussions have gone on for the past year concerning ways in which the private registries and the NMDP might better coordinate our efforts. *Attachment X* outlines a proposal which, I believe, can help to reduce the frustration of families desperately looking for a compatible unrelated donor. This proposal simply calls for the NMDP and the private registries to exchange preliminary search results at no cost to the patient and/or the patient's insurance company.

I give you my determined word of honor that I will not rest until all registries are merged into an integrated, well-functioning system, here in

the U.S. and worldwide. The four members of our Board who became involved because of a family situation -- including our wise and spirited Chairman, Admiral Zumwalt-- as well as the respected Board members from transplant centers, continue to feel a great urgency to minimize the distress for patients. While many of our transplant centers search all registries now available, the system still needs to be streamlined. I will continue in my efforts for this result. It is a high priority of our entire Board.

Internationally and nationally, NMDP is emerging as the umbrella organization consisting of a vast array of people and organizations committed to matching patients to donors. This program is multi-faceted and you will hear of times when our system, with all of its participants, does not yet function as smoothly as it should. But we are evolving and are responding quickly to patients and hope to have a full, streamlined system in place within one year nationally, four years internationally.

5. Meeting the Challenge of Funding NMDP Registry Expansion
Fundraising in the private sector to cover the cost of HLA typing continues to be a challenge. We are successfully accomplishing a streamlining of fundraising activities with the help of Life-Savers Foundation of America, NMDP's community recruitment group. Headed by Dr. Rudi Brutoco, Life-Savers has already raised over five million dollars, much of it through family drives but also through the generosity of thousands of Americans who just want to help our efforts in general. Dow Corporation has given us invaluable support through development of recruitment materials, as have other companies and individuals.

The National Marrow Donor Program is in the final stages of becoming a free-standing, non-profit organization, reporting directly to the National Heart, Lung, and Blood Institute, under the direction of Dr. Lenfant.

6. Fully Typing (HLA- A,B,DR) the NMDP Registry
About three quarters of our Registry is only HLA A,B typed. To determine a full match, an HLA DR test must also be done. Currently, patients and their insurance companies bear the brunt of the cost of DR typing preliminary matches. This is inefficient because patients, who don't have time to wait, must wait for the results of the added test as well as pay for it, even when potentially compatible donors are not located. Our goal is to prospectively DR type the whole registry. We've begun this process by urging our corporate sponsors to fully type their employees -- the difference between a

$75 and $150 per employee cost has prohibited some but we will continue in our efforts. We've also been wrestling with our budget and delaying other priorities to allow for some funds to be diverted for DR typing. Still, to fully type the whole current file, a major infusion of funds is necessary *[Attachment XI]*.

Conclusion

The list of other challenges before us is long. It includes studying and responding to Registry attrition, international standards and expansion and continued protection of the health, safety and anonymity of the donor *[Attachment XII and brochures]*.

Our Program has gone through phenomenal growth recently. While there have been unforeseen difficulties to surmount, the fact remains that we have been extremely successful in fulfilling our mission. Sometimes it has taken a great amount of tenacity, sometimes bullheadedness -- usually with a sense of urgency for those patients we are losing -- but always with compassion for the patient and families and awe at the generosity of spirit demonstrated by our donors and prospective donors.

Congress can be proud of the integral role it has played. Senators Gore, Laxalt, Bennett Johnson and Hatfield and Congressmen Young and Waxman helped us mark out the trail we have now blazed. Many other members of Congress, including you and your staff, Senator Kennedy, continue to help us along the way. Without you, this wonderful story of help and hope would not be possible.

We must all grieve for Judie, Christopher, Joanne and the hundreds of others who ran out of time while they were waiting for that miracle match. Because of Grant, Jolene, Alison and thousands of others, we must all maintain our sense of urgency to move as quickly as we can to find the strangers who can offer them the gift of life. But for Patrick, the valedictorian of his high school class, for Diana, the mother of four, for Shaina and Christian, children who now have a future, and for many others rejoicing with their families as they share a life together, I must say thank you.

United States Senate
Committee on Labor and Human Resources
Continued Testimony
of Robert C. Graves, D.V.M.
Vice Chairman, Board of Directors
National Marrow Donor Program
March 30, 1990 for March 21, 1990 Hearing

As I stated in my previous testimony, the phenomenal success of the National Marrow Donor Program (NMDP) is one which can and should be shared by our whole nation. The desperate plea of families still searching for a match is a plea which has moved many Americans to action. I commend you for allowing these pleas to be heard in the halls of our Capitol.

One of the harshest statements made by Mr. Atlas during his testimony was that the registry is being built "on the backs of dying children and their families". While it cannot be attributed to any Director of the NMDP, our Board does acknowledge our success has been in large part, due to the exhaustive and desperate efforts of, in Senator Mikulski's words, "the determined Moms and Dads" of stricken patients. Furthermore, for patients of minority backgrounds, such as Jocelyn, the hope of finding a matching stranger has not been real because of the low numbers of NMDP minority volunteers.

The Board of the National Marrow Donor Program has asked and received from Congress the funds needed to build the infrastructure to accomplish the search services needed to perform unrelated marrow transplants in an ethical yet practical manner.

Growing experience indicates that unrelated marrow transplantation is a viable medical therapy. It is appropriate that we offer an equal chance of hope and help for all American in need of a marrow transplant. It may well be prudent for Congress to provide the necessary funds to type an adequate number of volunteer donors. However, even after attaining the NMDP goal of a pool of 250,000 United States volunteers and a million worldwide, we may still not be able to provide everyone in need with a matched stranger. Some patients will have such an extremely rare mix of antigens, that there will not be a match available. We would hope the number of such patients will be small.

Regarding the testimony offered by Ms. Joan Keller and Ms. Joanne Raymond, I have nothing but heartfelt praise for their efforts. The private registries of the world, including the Anthony Nolan in England, were started and maintained by people just like these two dedicated women, long before the NMDP was established. It is regrettable that any difference in philosophy could exist between a government-funded project managed by its knowledgeable and prestigious directors and the private registries. We all have the same goal. I pledge again that through your efforts in bringing these philosophical differences into the open and our subsequent correspondence, the Board of the NMDP stands ready and willing to work with the private registries. However, we stand firm that there must be no departure from the highest standards of medical care. We must be sure that an unrelated marrow transplant is indeed the appropriate treatment for all patients referred for a donor search. We must be certain that all potential donors have a complete and confidential medical evaluation performed by an impartial third party physician before proceeding to an aspiration.

Because of my involvement in this effort, I may be able to offer a broad perspective on the history of unrelated marrow transplantation:

It really starts with my daughter, Laura and her donor, Franci and the unwavering faith of Drs. Donnall Thomas and John Hansen of the Fred Hutchinson Cancer Research Center in Seattle Through their combined efforts, in the late 1970s, marrow transplantation between unrelated but HLA identical people became a very real hope for many. The first private registry and matching service in the United States began in my basement.

As time went on, after many setbacks, not the least being turned down by the old Department of Health, Education and Welfare and, more recently by the National Institutes of Health, our path in establishing the NMDP finally led to the U.S. Navy. A board of directors was convened as called for in the Navy contract with the Board reporting back to the Navy. Operations began in the fall of 1987.

Today, we are proud of our accomplishments. We are lauded around the world as the model for transplantation coordination.

The Board now reports to Dr. Claude Lenfant, Director of the National Heart, Lung, and Blood Institute. We are establishing an excellent working arrangement with Dr. Lenfant. The Board of the NMDP continues its autonomy and allows its aggressive nature to manifest itself to the fullest.

I can assure you, if Congress sees fit to establish a higher level of funding, it will also be leveraged in the private sector by NMDP's community recruitment group, LIFE-SAVERS Foundation of America. I can also assure you that any funds will be expended in a very practical and productive manner.

Thank you for this opportunity to address a grassroots program to which I have devoted over a decade of time and resources. Because of the help and kindness of many, we have provided hope for many patients. May the amount of hope and help continue to multiply.

Attachment I

National Marrow Donor Program
Mission Statement

The following NMDP mission statement is contained in the handbook issued to participating centers:

The primary mission of the National Marrow Donor Program and its donor registry is to make unrelated marrow transplants available as a life-saving therapy. The goal of the program is to be able to provide donors for as many patients as possible by establishing a file of significant size of HLA-A, B and DR typed donors of diverse ethnic and racial origin in the United States. The NMDP will also work to promote cooperation with marrow donor programs in other countries.

A second mission of the National Marrow Donor Program is to develop policies and procedures which are in the best interests of marrow donors and recipients. The National Marrow Donor Program will promote marrow donation by working to establish policies and procedures concerning the recruitment of marrow donors, the collection of marrow and the care of donors following marrow collection. These policies and procedures must promote donor safety, comfort, well being and confidentiality.

A third mission of the NMDP is to participate in research concerning the clinical outcome of transplants with unrelated marrow donors. These retrospective and prospective studies will be designed to establish the clinical efficacy of unrelated marrow transplants, define the optimum technique for carrying out the transplants, assess the physical, psychological and social impact of the marrow collection process on the donors, and encourage basic research in the genetics and biology of transplantation.

A fourth mission of the NMDP is to promote equal and prompt access to marrow donors for all people in the United States and foreign countries needing marrow transplants with unrelated donors. Particular attention will be directed toward eliminating financial barriers facing patients needing a marrow transplant from an unrelated donor.

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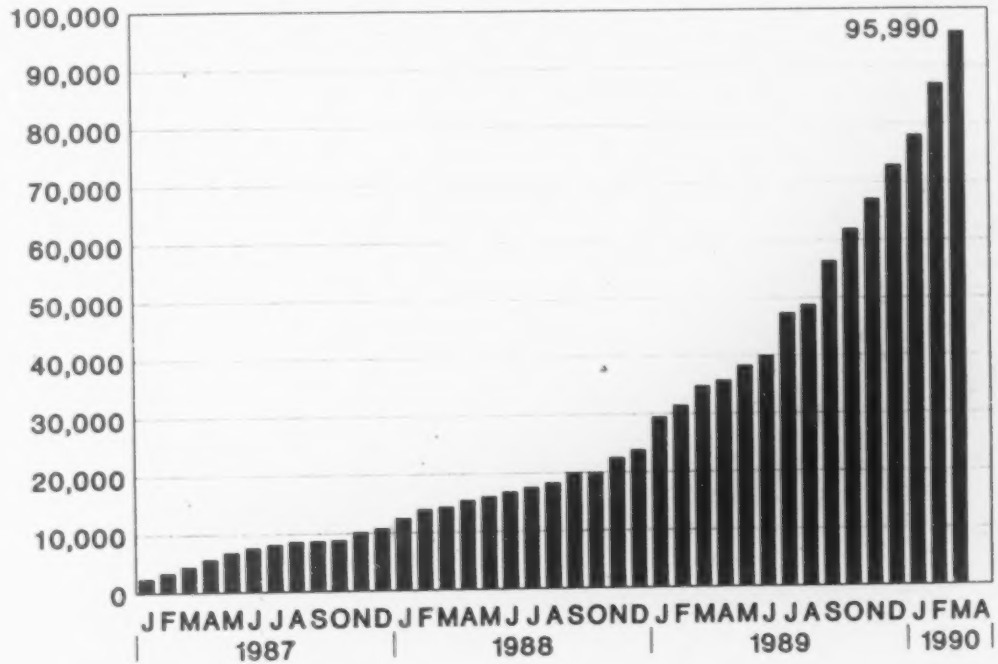
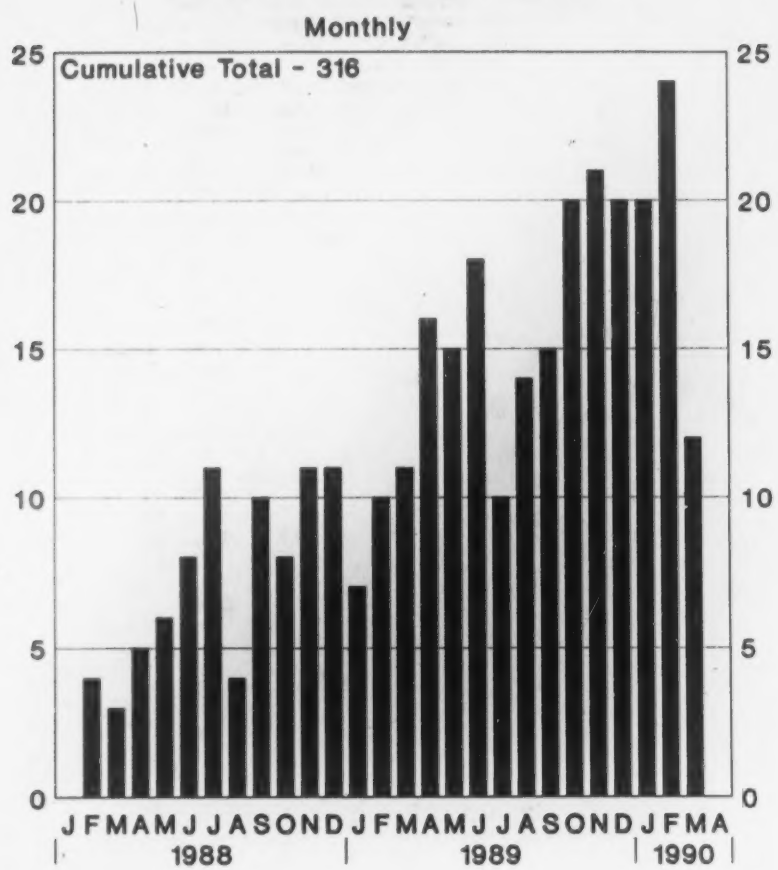
VOLUNTEERS WILLING TO DONATE MARROW



Source: National Marrow Donor Program
March 19, 1990

Attachment III

NMDP SEARCHES REACHING TRANSPLANT



Source: National Marrow Donor Program
March 19, 1990

NMDP DONOR CENTER MEDICAL DIRECTORS AND COORDINATORS

CENTER	CITY	MEDICAL DIRECTOR	COORDINATOR
United Blood Services	Scottsdale, AZ	Thomas B. Wiltbank, M.D. (602) 949-1412, ext. 258	Judy Bartholomeaux, R.N., BSN (602) 949-1412, ext. 260
University Medical Center	Tucson, AZ	Douglas W. Huestis, M.D. (602) 694-6269	H. Neal Smith, B.A, BB (ASCP) (602) 694-6269
American Red Cross Los Angeles-Orange Counties Region	Los Angeles, CA	Steven Kleinman, M.D.. (213) 739-5529	Bunnie Foxcroft (213) 739-4594
Satellites: Alhambra Anaheim Arcadia Burbank Canoga Park (2) Compton Covina Culver City Downey (2) Duarte E. Los Angeles Fullerton Glendale Glendora Harbor City Huntington Beach Inglewood (2) Lancaster (2) La Verne Long Beach (2) Los Angeles (6) Newport Beach Northridge Orange Panorama City Pasadena (3) Pomona (2) San Pedro Santa Ana Santa Monica (3) South Gate Torrance (3) Valencia Van Nuys West Covina West Hollywood West Los Angeles Westlake Westwood UCLA Medical Center Whittier (2)			
City of Hope National Medical Center	Duarte, CA	Stephen Forman, M.D. (818) 359-8111 ext. 2404	Barbara Littrell (818) 301-8168
Peninsula Memorial Blood Bank	Burlingame, CA	Keith L. Duncan, M.D. (415) 697-4034	Ellen Kross, R.N. (415) 697-4034
Alameda Contra Costa	Oakland, CA	M. Silvija Hoag M.D. (415) 654-2924 ext. 6102	Anne Brewster, R.N. (415) 654-2924
Stanford University Blood Bank	Palo Alto, CA	F. Carl Grumet, M.D. (415) 723-7994	Diane L. Hill (415) 723-5532

CENTER	CITY	MEDICAL DIRECTOR	COORDINATOR
Sacramento Medical Foundation Blood Center	Sacramento, CA	Paul V. Holland, M.D. (916) 456-9008	Sharon Redding (916) 456-1500, ext. 367
Satellites: Lake Tahoe, NV Chico, NV Grass Valley, NV Citrus Heights, NV Marysville, NV Vacaville, NV Valley Hi Blood Center Truckee, NV			
Blood Bank of the San Bernardino & Riverside Counties	San Bernardino, CA	Arthur J. Silvergleid, M.D. (714) 885-6503	Jean Blaylock (714) 885-6503
Satellites: Riverside, CA Ontario, CA			
San Diego Blood Bank	San Diego, CA	Victor J. DePratti, M.D. (619) 296-6393, ext. 232 Rebecca Fleck, M.D. (Asst.) (619) 296-6393, ext. 254	Christine Sloan, RN (619) 296-6393, ext. 295
Irwin Memorial Blood Bank	San Francisco, CA	Herbert A. Perkins, M.D. (415) 567-6400 ext. 401	Rosie Lamoreaux (415) 567-6400, ext. 414
Satellites: Downtown, San Francisco, CA Fairfield, CA San Rafael, CA Novato, CA Vallejo, CA			
Heart of America Bone Marrow Donor Registry, Inc.	San Francisco, CA	Frederick Harris (913) 967-5276	Fran McDermott (415) 647-1980

CENTER	CITY	MEDICAL DIRECTOR	COORDINATOR
American Red Cross Central California Region	San Jose, CA	J. Lawrence Naiman, M.D. (Muriel) (408) 292-6242	Edie Fields, BSN (408) 292-6242, ext. 237
Belle Bonfils Memorial Blood Center	Denver, CO	Robert G. Chapman, M.D. (303) 355-7366 ext. 21	Tony Steele (303)355-7366
Rocky Mountain Bone Marrow Center	Fort Collins, CO	Christopher Staszak, M.D. (303) 490-4184	Nancy McConell (303) 490-4184
American Red Cross Connecticut Region	Farmington, CT	Richard L. Edwards, M.D. (203) 678-2809	Debra R. Yanke (203) 678-2865
Satellites: Public Health Dept.	Stamford, CT		Joan Davey (203) 977-4396
American Red Cross Washington Region	Washington, DC	James Aubuchon, M.D. (202) 728-6478 or 639-3263	Debbie Caffrey (202) 728-6663
Civitan Regional Blood Center	Gainesville, FL	Bruce Stechmiller, M.D. (904) 373-0933	Jeff Durst, MT, EMT II (904) 377-6905, ext. 46 (904) 395-0482
Gulf Stream Regional Blood System, Inc.	Lauderhill, FL	Charles Rouault, M.D. (305) 735-9600	J.T.L. Lane and Sheila Pugh (305) 735-9600
Satellites: Lakeland Miami Delray Beach East-Fort Lauderdale Hendry-Clewiston	Veron Branch Mid-County - Boca Rato Martin County Palm Beach Garden North Pampano Beach	Okeechobee Palm Beach South County - Boca Raton South-Pembroke Pines West Coral Springs	

CENTER	CITY	MEDICAL DIRECTOR	COORDINATOR
Jacksonville Marrow Transplant Donor Registry	Jacksonville, FL	Ron Charlton, Ph.D. (904) 366-7900	Pamela Owens, MT (ASCP) (904) 366-7900
South Florida Regional Blood Service	Miami, FL	Bruce Lenes, M.D. (305) 326-8888	Leslie Manzini (305) 326-8888, ext. 631
Central Florida Blood Bank	Orlando, FL	Neil Newberg, M.D. (407) 849-6100	Nancy J. Peterson, Mt (ASCP) SBB (407) 849-6100 ext.200
Community Blood Bank	St. Petersburg, FL	Michael Lynch, M.D. (813) 327-0168	Linda D. Smith, R.N. (813) 327-0168
American Red Cross Atlanta Region	Atlanta, GA	Alfred J. Grindon, M.D. (404) 881-9800	Niles B. Reese, MT (ASCP) (404) 881-9800, ext. 418
Hawaii Bone Marrow Donor Registry St. Francis Medical Center	Honolulu, HI	Young Paik, M.D., F.A.C.P. (808) 524-6619 or 547-6536	June Kuroda, MT (ASCP) MSW (808) 524-6619
LifeSource	Glenview, IL	Ennio Rossi, M.D. (708) 298-9660	Joy Watanuki, R.N. (708) 298-9660
American Red Cross Heart of Illinois Region	Peoria, IL	Carol Talacki, M. D. (309) 674-7171	Pamela Eigsti, MT (ASCP) Nora Sullivan (309) 674-7171
Satellites: Aledo, IL Bloomington, IL Clinton, IL Fairbury, IL	Kankakee, IL Kewanee, IL Ottawa, IL Paris, IL	Pekin, IL Peru, IL Rock Falls, IL Streator, IL	
American Red Cross Fort Wayne Region	Fort Wayne, IN	Margaret J. Ball, M.D. Ranie Koshy, M.D.	Rosemarie Strothman (219) 480-8266

CENTER	CITY	MEDICAL DIRECTOR	COORDINATOR
Central Indiana Regional Blood Center **Satellites:** Lafayette, IN Terre Haute, IN Anderson, IN	Indianapolis, IN	Alessandra G. Thelia, M.D. (317) 926-2381	Mary Swinney, R.N. (317) 927-1679
American Red Cross Midway-Kansas Chapter **Satellites:** Lawrence	Wichita, KS	William M. Palko, M.D. (316) 268-0817	Brent Yoder, MT, SBB (316) 268-0817
Central Kentucky Blood Center	Lexington, KY	C. Darrell Jennings, M.D. (606) 276-2534	Judi Baker, R.N. (606) 276-2534
Blood Center for S.E. Louisiana	New Orleans, LA	David Smith, M.D. (504) 524-1322 (INACTIVE)	Karen Bergeron (504) 524-1322 (INACTIVE)
Dana-Farber Cancer Institute	Boston, MA	Kenneth C. Anderson, M.D. (617) 732-3092	Colleen O'Neil (617) 732-3206
American Red Cross Northeast Region **Satellites:** Bangor, ME Methuen, MA Peabody, MA Pittsfield, MA Portland, ME Springfield, MA Worcester, MA	Dedham, MA	Mark Popovsky, M.D. (617) 461-2075	Deborah F. Katcher-Buckley, MT (AS (617) 461-2075
Johns Hopkins Hemapheresis Treatment Center	Baltimore, MD	Hayden G. Braine, M.D. (301) 955-8841	Lois Hoffer, R.N. (301) 955-6347

CENTER	CITY	MEDICAL DIRECTOR	COORDINATOR
American Red Cross Chesapeake Region	Baltimore, MD	Kate Rotkho, M.D. (301) 467-9905	Jenny Zink, R.N. (301) 764-4621 ext. 646
NIH Clinical Center Blood Bank	Bethesda, MD	Harvey G. Klein, M.D. (301) 496-9702	Bernice Loiacono (301) 496-0572/496-4321
American Red Cross Southeastern Michigan Region	Detroit, MI	Detroit, MI (313) 494-2783	Shobha Shah, M.D. Jacque Ne (313) 494-2712
Satellites: Ann Arbor, MI Bloomfield, MI Dearborn, MI Livonia, MI Oak Park, M	Port Huron, MI Roseville, MI Southgate, MI Sterling Heights, MI		
Grand Valley Blood Program	Grand Rapids, MI	C. Alan Payne, M.D. (616) 774-2300	Brenda Tate (616) 776-1876
Satellites: Bay City, MI Midland, MI Saginaw, MI			
American Red Cross Great Lakes Region	Lansing, MI	John Penner, M.D. (517) 484-7461	Marilyn Frankenberger, R.N., BSN (517) 484-7461
Saginaw Valley Blood Program	Saginaw, MI	C. Allen Payne (616) 774-2300	Judy Lumsden (517) 755-0973
American Red Cross St. Paul Region	St. Paul, MN	David Stroncek, M.D. (612) 291-4623	RoxAnn Strand/Cindy Hofkes (612) 291-4604 or (612) 291-6732
Satellites: Eau Claire, WI			

CENTER	CITY	MEDICAL DIRECTOR	COORDINATOR
Heart of America Bone Marrow Donor Registry, Inc.	Raytown, MO	Frederick J. Harris (913) 967-5276	Karen Thomas/Sandy Harris (816) 333-0305
American Red Cross Missouri-Illinois Region (INACTIVE)	St. Louis, MO	Parveen Ahmed, M.D. (314) 658-2071	TO BE NAMED
American Red Cross Carolinas Region	Charlotte, NC	Paul Jenner, M.D. (704) 376-1661	Kay Piercy, R.N. (704) 376-1661
Satellites: Winston-Salem, NC Raleigh, NC Durham, NC			
American Red Cross Midwest Region	Omaha, NE	Donald Skoog, M.D. (402) 341-2723	Paulette Dellovechio, BA, MT (ASCP) (402) 341-2723
Satellites: North Platte, NE			
New Jersey HLA Registry Foundation	Oradell, NJ	Elie Katz, Ph.D. (201) 265-2623	
United Blood Services	Albuquerque, NM	Kenneth J. Smith, M.D. (505) 843-6227	Beverly Ferdinando, R.N. (505) 843-6227
American Red Cross Northeastern New York Region	Albany, NY	Hany Kamel, M.D. (518) 462-7461	Dawn Montavon (518) 462-7461
New York Blood Center	New York, NY	Joan Uehlinger, M.D. (212) 570-3239	Janet DiNapoli, MT (ASCP), SBB (212) 570-3083
Satellites: Long Island New Brunswick, NJ Valhalla, NY			

CENTER	CITY	MEDICAL DIRECTOR	COORDINATOR
American Red Cross Rochester Region	Rochester, NY	Joanna Heal, M.R.C.P. (716) 461-9800	Carolyn N. Laque (716) 461-9800, ext. 305
Satellites: Binghamton, NY			
American Red Cross Syracuse Region	Syracuse, NY	Harold Lamberson, M.D. (315) 425-1641	Ellyn Lentz Karen Bostwick Bowman (315) 425-4818
Satellites: Ithaca, NY Utica, NY Watertown, NY			
University of Cincinnati Hoxworth Blood Center	Cincinnati, OH	Kamala Balakrishnan, M.D. (513) 569-1114	Lynn Robert Whitacre, MS (513) 569-1114
American Red Cross Northern Ohio Region	Cleveland, OH	Louise J. Keating, M.D. (216) 444-3345-Hospital	Caroline Kean (216) 391-9800
American Red Cross Central Ohio Region	Columbus, OH	Mary E. Wissel, M.D. (614) 253-7981	Ann May (614) 253-7981
Satellites: Mansfield, OH Newark, OH			
American Red Cross Northwest Ohio Region	Toledo, OH	Peter M. Lau, M.D. (419) 248-3331	Carol Zuber Kathleen Feicht, MT, SBB (419) 248-3331 ext. 255 and 314
The Sylvan Goldman Center Oklahoma Blood Institute	Oklahoma City, OK	Ron Gilcher, M.D. (405) 232-0670 ext. 500 James W. Smith, M.D., Ph.D. Asst. Med. Dir (405) 232-0670 ext. 611	Linda Chandler, P.A. (405) 239-7638

CENTER	CITY	MEDICAL DIRECTOR	COORDINATOR
American Red Cross Oklahoma Region	Tulsa, OK	Duke O. Kasprisin, M.D. (918) 831-1171	Donna Daves/Andrea Perisho (918) 831-1182
American Red Cross Pacific Northwest Region	Portland, OR	Frans Peetoom, M.D., Ph.D. (503) 284-2774 or 284-5005	Mary Gayle Bennett (503) 280-1446
Satellites: Bend, OR Coos Bay, OR Corvallis, OR Gresham, OR Lincoln City, OR	Medford, OR Newport, OR St. Joseph's Vancouver, WA The Dalles, OR		
American Red Cross Johnstown Region	Johnstown, PA	Richard C. Block, M.D. (814) 533-2769	Jean Smith (814) 536-8723, ext. 40
American Red Cross Penn-Jersey Region	Philadelphia, PA	Jay Herman, M.D. (215) 299-4877	Charlene Rose (215) 299-4139
Satellites: Wilkes-Barre, PA			
Central Blood Bank of Pittsburgh	Pittsburgh, PA	Joseph E. Kiss, M.D. (412) 622-7294	Carol Ranallo/Ethel Maloney (412) 456-5595
Satellites: Pittsburgh (7) New Kensington Washington	McMurray Monroeville		
American Red Cross South Carolina Region	Columbia, SC	Todd Kolb, M.D. (803) 251-6000	Alison Moore, M.T. (803) 256-2301, ext. 80
Life Blood Mid-South Regional Blood Center	Memphis, TN	Edward Scott, M.D. (901) 522-8585	Priscilla Youd, R.N. (901) 522-8585

CENTER	CITY	MEDICAL DIRECTOR	COORDINATOR
American Red Cross Tennessee Valley Regions	Nashville, TN	Charles Wallas, M.D. (615) 343-9144	Carol Santoro (615) 327-1931 ext. 336
The Blood Center at Wadley Institutes	Dallas, TX	Norwood Hill, M.D. (214) 351-8560	Jill Skupin, CHS (ABHI) (214) 351-1360
Satellites: Abilene, TX Laredo, TX Midland, TX Olney, TX Wichita Falls, TX			
American Red Cross Vermont-New Hampshire Region	Burlington, VT	Robert G. Westphal, M.D. (802) 658-6400	Alice Adams, R.N. (802) 658-6400
American Red Cross Tidewater Region	Norfolk, VA	Stephen H. Leech, M.D., Ph.D. (804) 628-3000	Harriet Mallori (804) 446-7730
Spokane & Inland Empire Blood Bank	Spokane, WA	George W. Schneider, M.D. (509) 624-0151	Rita Smith (509) 624-0151
Puget Sound Blood Center	Seattle, WA	Patrick G. Beatty, M.D., Ph.D. (206) 467-4920	Robin Fowler (206) 292-1897
Satellites: Eastside Northend Southcenter			
Tri-State American Red Cross	Huntington, WV	Mabel Stevenson, M.D. (304) 522-0328	Nancy Peterson, MT (ASCP) CHS (304) 522-0328

CENTER	CITY	MEDICAL DIRECTOR	COORDINATOR
American Red Cross Badger Region	Madison, WI	Gary A. Becker, M.D. (608) 233-9300	Carla Moore (608) 233-9300
Satellites: Green Bay, WI Dubuque, WI			
Blood Center of S.E. Wisconsin	Milwaukee, WI	Jay E. Menitove, M.D. (414) 933-5000 ext. 267	Gayle Bass (414) 937-6267, 937-6368
Satellites: Brown Deer, WI Greenfield, WI Kenosha, WI Racine, WI Waukesha, WI Wauwatosa, WI West Bend			
Hadassah Medical Organization (Pending U. S. Government Approval)	Jerusalem, Israel	Chaim Brautbar, Ph.D. 972-2-428772	Anat Sayag 972-2-429772
The Netherlands EuropDonor Foundation	Leiden,The Netherlands	Jon van Rood, M.D. (71) 263800 or 264008	Aad van Leeuwen, Ph.D. 011-31-71-263800

(Rev. February 22, 1990)

NMDP TRANSPLANT CENTERS

CENTER	CITY	CONTACT PHYSICIAN	COORDINATOR
City of Hope National Medical Center	Duarte, CA	Stephen Forman, M.D. (818) 359-8111, ext. 2404 Gerhard M. Schmidt, M.D. (818)359-8111, ext.2691	Barbara Littrell (818) 359-2405, beeper 5203
Children's Hospital of Los Angeles	Los Angeles, CA	Carl Lenarsky, M.D. (213) 669-2546	Jan Cipkala-Gaffin (213) 669-4558
Kaiser Permanente	Los Angeles, CA	Peter M Falk, M.D. (213) 667-5306	
University of California (UCLA)	Los Angeles, CA	Richard Champlin, M.D. (213) 825-9677	James Gajewski, M.D. (213) 825-6301 (page) Lynne Hunt (213) 206-6046, ext. 833
Stanford University Medical Center	Stanford, CA	Karl Blume, M.D. (415) 723-4000	Anne Thomasmeyer (415) 723-7979
University of California-San Francisco Department of Pediatrics	San Francisco, CA	Mort Cowan, M.D. (415) 476-2188	Linda Z. Abramovitz, R.N., MSN (415) 476-2188, Beeper 498
Vancouver General Hospital	Vancouver, British Columbia, Canada	Gordon L. Phillips, M.D. (604) 875-4161	Janice King (604) 879-9400
Georgetown University Hospital Lombardi Cancer Research Center	Washington, D.C.	Thomas R. Spitzer, M.D. (202) 687-2213	Anita Nida (202) 687-2213
Shands Hospital, University of Florida	Gainesville, FL	Roy Weiner M.D. (904) 392-8530 Co-Director (Peds) John Graham-Pole, M.D.	Jan Luzins/Paul Phillips, R.N. (904) 395-0042 or. 9934 (904) 395-0111 or 9929

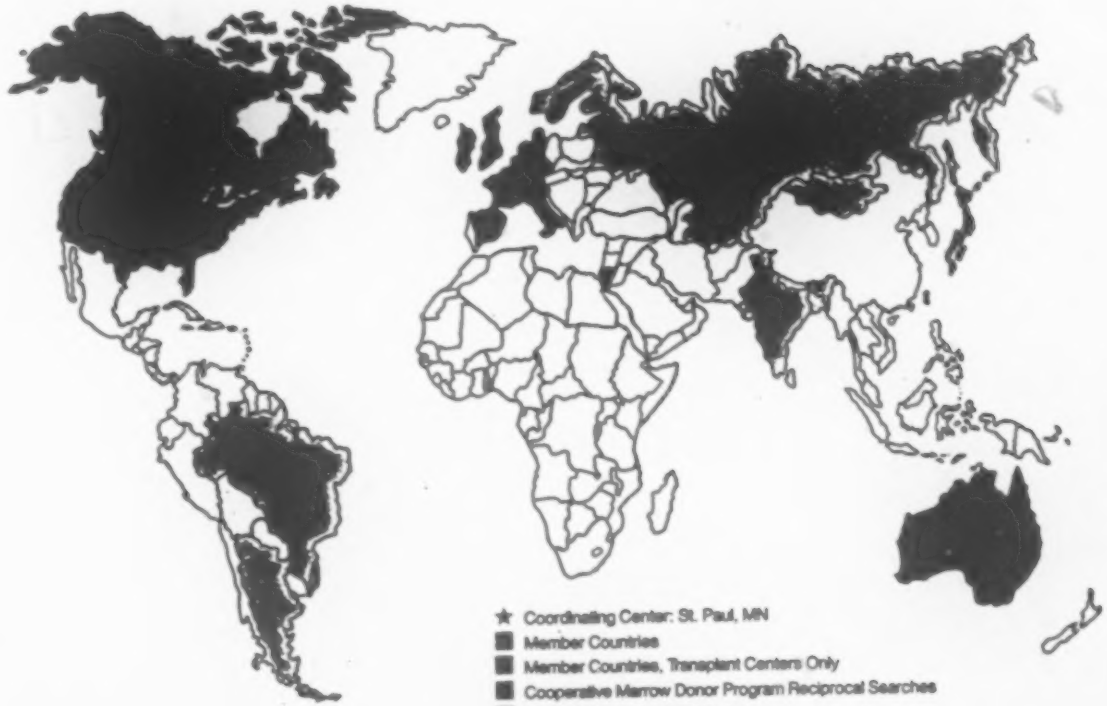
CENTER	CITY	CONTACT PHYSICIAN	COORDINATOR
All Children's Hospital University of Florida	St. Petersburg, FL	Robert A. Good, M.D., Ph.D. (813) 892-4470	Pam Kiefhaber (813) 892-4234
University of Iowa Hospitals and Clinics	Iowa City, IA	Roger D. Gingrich, M.D., Ph.D. (319) 356-3425 Michael Trigg, M.D. (319) 356-1608	Colleen Chapleau (319) 356-3211 or 3337
University of Indiana Hospital Indiana University Medical Center	Indianapolis, IN	Guido Trico, M.D., Ph.D. (317) 274-0843	Helen Welsh/Paulette Camden (317) 274-0436 , Beeper 1100
University of Kentucky Medical Center	Lexington, KY	P. Jean Henslee, M.D. (606) 233-5768	Marianne H. Clark (606) 233-5537
Dana Farber Cancer Institute	Boston, MA	Joseph Antin, M.D. Eva Guinan, M.D. (617) 732-3564	Margaret Provost (617) 732-3864
Johns Hopkins Oncology Center	Baltimore, MD	Rein Saral, M.D. (301) 955-8840	Lois Hoffer, R.N. (301) 955-8832
Wayne State University Harper-Grace Hospitals	Detroit, MI	Lyle L. Sensenbrenner, M.D. (313) 745-9160	Patricia Steele, R.N. (313) 993-0205 745-5111 Beeper 5457
University of Minnesota Hospital and Clinic	Minneapolis, MN	Philip McGlave, M.D. (612) 624-0123	Joanne Howard, R.N. Sharon Roell, R.N. (612) 626-2800
University of Nebraska Medical Center	Omaha, NE	Phyllis Warkentin, M.D. (402) 559-7282	Mary Benedetto (402) 559-7257
Memorial Sloan-Kettering Cancer Center	New York, NY	Richard J. O'Reilly, M.D. (212) 639-5957	Carol W. Landrey (212) 639-7432

CENTER	CITY	CONTACT PHYSICIAN	COORDINATOR
Cleveland Clinic Foundation	Cleveland, OH	Brian J. Bolwell, M.D. (216) 444-8375	Karen Sands, R.N. (216) 444-2200
Children's Hospital Medical Center	Cincinnati, OH	Richard E. Harris, M.D. (513)559-4266	Peggy Kaiser (513) 559-4200
Ohio State University	Columbus, OH	Peter J. Tutschka, M.D. Edward Copelan, M.D. (614) 293-8000	Linda K. Grail (614) 293-8939
Children's Hospital of Philadelphia	Philadelphia, PA	Charles S. August, M.D. (215) 596-9100	Beth Sturgill, R.N. (215) 590-3681
Hahnemann University Hospital	Philadelphia, PA	Stephen I. Bulova, M.D. (215) 448-8026	Judith Moudy (215) 448-7050, Beeper 1039, also (215) 448-8026
Montefiore Hospital University of Pittsburgh	Pittsburgh, PA	Richard K. Shadduck, M.D. (412) 648-6000	Patricia Schaefer, R.N. (412) 648-6000, ext. 6413 Beeper 599
Vanderbilt University Medical Center	Nashville, TN	Steven Wolff, M.D.	Van Welch, R.N. (615) 322-2829
University of Texas Health Science Center	San Antonio, TX	Thomas Williams, M.D. (512)567-5269	Fran Prenzeler
University of Virginia	Charlottesville, VA	F. Marc Stewart, M.D. (804)924-1693	Karin Eshleman, R.N. (804)924-1693
Fred Hutchinson Cancer Research Center	Seattle, WA	John A. Hansen, M.D.. (206) 467-5111	Michelle Swofford/Lori Hubbard (206) 467-5221
Seattle Veteran's Administration Medical Center	Seattle, WA	Jack Singer, M.D. (206) 764-2139	Pam Jones (206) 764-2139

CENTER	CITY	CONTACT PHYSICIAN	COORDINATOR
University of Wisconsin	Madison, WI	Walter Longo, M.D. (608) 263-4690	Bridget Flynn, M.A. (608) 263-8628
Medical College of Wisconsin Milwaukee County Medical Complex	Milwaukee, WI	Robert C. Ash, M.D. (414) 257-5251	Barb Prasser, R.N. (414) 257-7191
St. Vincent's Hospital (Pending U.S. Government Approval)	New South Wales, Australia	Kerry Atkinson, M.D.	To be named
Hadassah Medical Organization (Pending U.S. Government Approval)	Jerusalem, Israel	Chaim Brautbauer, Ph.D. 972-2-428-772	Anat Sayag 972-2-429-772
University Hospital (Pending U.S. Government Approval)	Leiden, The Netherlands	Jon van Rood, M.D. 31-71-263600	Aad van Leeuwen, Ph.D. 31-71-263600
Karolinska Institutet (Pending U. S. Government Approval)	Stockholm, Sweden		

Revised 02/22/90

National Marrow Donor Program: GLOBAL HOPE



★ Coordinating Center: St. Paul, MN
Member Countries
Member Countries, Transplant Centers Only
Cooperative Marrow Donor Program Reciprocal Searches
Formal Discussions Underway
? Informal Inquiries

Total 66 Donor Centers — 32 Transplant Centers

NATIONAL MARROW DONOR PROGRAM
Attachment VII

COMMUNITY RECRUITMENT DATA ENTRY AUTOMATION PROPOSAL

Activity

1. Community Recruitment Event

   - Potential donors sign consents, complete demographics forms (bar-coded, computer optics scannable format), and give blood for typing (tubes are bar-coded).
   - Blood is sent to laboratories by overnight express.
   - Donor information is sent to Central Processing Center by overnight express.

2. Central Processing Center optically scans donor forms creating partial donor records.

3. Laboratory begins tissue typing using bar codes as donor IDs.

4. Laboratory completes tissue typing and transmits typing data to Central Processing Center by computer transfer.

5. Central Processing Center computer matches tissue typing with partial donor records to create complete donor records.

6. Central Processing Center transmits complete donor records to designated Donor Centers by computer transfer.

7. Central Processing Center transmits complete donor records to Registry for file update and search re-runs.

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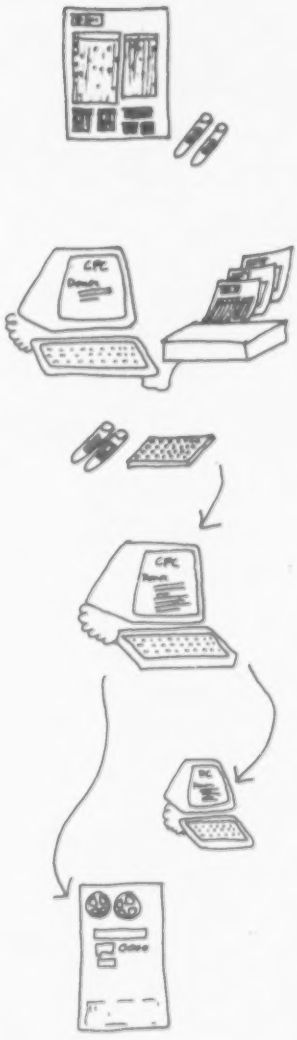

Attachment VIII

National Marrow Donor Program

ST. PAUL
PIONEER PRESS DISPATCH

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BONE MARROW DONORS

More help needed, for less desperation

Stories of desperate searches for bone marrow to renew the chance of life glide in and out of the daily news, selectively focusing on a particular patient. The most recent gripper comes from California, where Abe and Mary Ayala, a midlife couple, decided to have another baby in hopes it could donate marrow to their teen-age daughter, who is fighting leukemia. If there were more potential donors, there would be fewer of these wrenching tales.

There would be more opportunities for healing, both for those whose cases get the publicity and for those whose agonies never generate a headline. Creating more hope is the reason for Bone Marrow Donor Week, being observed this week in Minnesota.

A sensible bill put forward in the Legislature aims at increasing the number of potential donors registered by the National Marrow Donor Program, based at the American Red Cross in St. Paul. Legislation introduced by Sen. Gene Merriam, DFL-Coon Rapids, and Rep. Charlie Weaver, IR-Champlin, would allow all workers time off to be tested as potential donors and additional time to donate bone marrow if there's a patient match. To set an example on needed funding, the bill would pay lab fees, about $75 per person, for the first 200 state employees who agree to being registered.

More important than legislation, however, is individual commitment to participate. The Red Cross says the registry needs more donors to augment the ranks of the 87,000 people now registered. It needs more people of color, because donor matches are most likely to occur within racial groups and almost all racial minorities are underrepresented in the registry. And, as volunteers from the general public sign up, there will be a need for more funding to type these volunteers. Helping begins with a phone call to the American Red Cross at (612) 290-8937 for potential donors.

Bone Marrow Donor Week provides a time to think about making a decision that could be so terribly important to someone else.

The above opinions are those of the Pioneer Press Dispatch editorial board, directed by Ronald D. Clark, editorial page editor. Members are John T. Henry, chairman and publisher; Deborah Howell, editor; Robert J.R. Johnson, associate editorial page editor; Jerry Fearing, editorial cartoonist; and Ann Daly Goodwin, Glenda Holste, Denise Johnson and Michael Vitt, editorial writers.

National Marrow Donor Program
Attachment IX

MINORITY DONOR RECRUITMENT

In order to ascertain that the NMDP would be a resource for all Americans, minority recruitment became a high priority during fiscal 89/90. The following achievements are examples of this aggressive activity.

- Many groups became involved in minority recruitment on behalf of the NMDP.

  1) Many of the 66 Donor Centers around the United States made contacts within local minority communities and initiated recruitment activities in those communities.

  2) Sub-contracts were awarded to five Donor Centers to concentrate recruitment efforts on their whole blood donor population. Each of these centers designated specific minority groups as a target for their activities. These five centers and their designated minority communities are as follows:

     - o Wadley, Dallas, TX - African-American and Hispanic
     - o ARC, Portland, OR - Asian-American
     - o Blood Center, Sacramento, CA - Asian-American and Latino
     - o ARC, St. Paul, MN - African American
     - o Blood Center, New York, NY - African-American and Latino

  3) Life-Savers and Heart of America are recruitment organizations operating around the United States. Each began to focus more intently on minority recruitment during fiscal 89/90.

  4) Community-based minority recruitment organizations were established during 89/90. The Judie Davis Program and the Asian American Program were assisted in establishment and organization to pursue recruitment in the African-American and Asian-American communities respectively. $90,000 in NMDP funds was allocated to HLA-typing to support start-up activities of these two groups.

- Through the efforts of all these groups, and with the support of the NMDP staff, over 5,000 minority donors were recruited in 89/90. The donor file now contains the following members of minority donors:

African-American	:	2,958
Asian-American	:	2,240
Latino	:	1,199
Native-American	:	490
Other	:	490
Caucasian	:	60,672
Unknown	:	28,220
Total Donors		95,990

- A recruitment brochure has been specifically designed for the African-American community, one is under development for the Asian community, and translations of generic brochures into Spanish are in progress.

03/19/90

In planning minority recruitment for fiscal 90/91, budget constraints and the ongoing commitment of the NMDP to aggressively pursue minority recruitment require that we undertake a planning process to assure that all current activities continue with maximum effectiveness.

The following planning process has been proposed:

- Name members of Minority Recruitment Task Force (representatives from minority communities, recruitment organizations, public education consultants, and government).
- Focus groups to identify key concepts and educational strategies for each group. Four sessions (in major minority concentration communities) for each of three minority groups: Asian-, African-, and Native-American.
- Exit surveys at planned minority recruitment drives to assess motivation and media effectiveness.
- Public Hearing on Minority Recruitment to allow for input from all segments of population.
- Planning sessions for Task Force to determine
  - Guidelines for minority recruitment activities
  - Key concepts for each minority group
  - Definition of critical materials to be developed
  - Time frames and goals
  - Appointment of limited funds ($250,000 in fiscal 90/91)
  - Key community leaders from each minority group to serve as ongoing spokespersons for minority recruitment.

ATTACHMENT X

A PROPOSAL FOR A SYSTEM TO HELP PATIENTS NEEDING AN UNRELATED DONOR BONE MARROW TRANSPLANT

Prepared By The National Marrow Donor Program
March 21, 1990

It is the belief of the National Marrow Donor Program (NMDP) that every patient needing an unrelated donor marrow transplant should have access to information about resources available in our country - or elsewhere in the world - that may be able to help them. The following information and assistance should be readily available:

1. The National Heart, Lung and Blood Institute (NHLBI) should publish a directory of resources available to serve patients needing an unrelated donor marrow transplant. Such a directory might be distributed by the government, transplant centers and marrow donor centers.

2. Inquiries to the NMDP from patients, their families or the general public requesting information or assistance, will routinely include information on how the American Association of Bone Marrow Donor Registries (AABMDR) can be contacted. Similarly, AABMDR should routinely refer callers to NMDP.

3. A new system is proposed whereby "preliminary searches" - the periodic scan of a Registry database to determine whether a possible compatible unrelated donor is on file - will be forwarded by the NMDP to AABMDR and vice versa. Upon receipt of a preliminary search request, both Registries will agree to scan their databases at no charge to the patient, the referring Registry or any other party. The referring Registry will be notified promptly if there appears to be a possible compatible donor.

   If implemented, this system will assure that patients working with either the NMDP or AABMDR will be made aware that a possible compatible donor exists in the database of the other Registry. When this occurs, the patient can pursue possible compatible donors by following the usual protocols of the Registry where the donor is enrolled.

   NMDP stands ready to implement this new system immediately.

4. The NMDP has proposed in its work plan and budget for its 1990-91 fiscal year to develop a patient services/ombudsman function to: (a) help patients, their families and community-based physicians understand the resources available through the NMDP and others; (b) serve as a referral source to direct patients to transplant centers appropriate to their needs; and (c) assist patients and their families in working with transplant centers and/or resolving problems they may encounter with the system.

pm/DAS001

Attachment XI

THE PROJECTED COST OF HLA TYPING A REGISTRY OF 250,000 DONORS

National Marrow Donor Program

1. 150,000 additional U.S.A. donors are needed to reach the current goal of 250,000 donors.

2. The cost to HLA type 150,000 donors is as follows:

a. HLA A,B testing @ $75/Test	=	$11,250,000
b. The incremental cost of HLA DR testing done in conjunction with HLA A,B testing @ $85/Test*	=	12,750,000
		$24,000,000

3. The cost to complete the DR testing of existing donors who are already HLA A,B typed:*
71,000 @ $125/Test = $ 8,875,000

4. The total cost to achieve a Registry of 250,000 donors who are fully HLA A,B and DR typed = $32,875,000

*Currently most volunteers are HLA-DR typed on request by Transplant Centers for specific patients. The cost to patients for this typing is approximately $280 per donor.

pm/DAS009

Why donate marrow?

"I donated for a nine-year-old boy and since that time, there's been a ripple effect that just keeps going on forever. The boy, the family and I will never be the same again."

Sandra Holmes

"It's not a black or white thing, it's about people helping each other."

Gayle Bass

"When it comes right down to it -- life or death – there's no question. I just did the right thing, and I'd do it again."

Henry Cotten

For additional information, please contact:

The Judie Davis Marrow Donor Recruitment Program
(The African American Project)
1-800-628-1413

LIFE-SAVERS Foundation of America
1-800-999-8822

NATIONAL MARROW DONOR PROGRAM

100 South Robert Street
St. Paul, MN 55107
1-800-654-1247

Produced with a grant from the people at

DOW

Ten-year-old Lyn Moore was diagnosed with Aplastic Anemia over two years ago. Soon...

... he will need an unrelated marrow transplant because there is no other cure for Lyn's disease and no one in his family is a suitable match.

His only hope is that more African Americans will agree to register with the National Marrow Donor Program and that he will match one of the new volunteers. It's his only chance for a future.

Who needs marrow transplants?

Lyn Moore represents the more than 16,000 children and adults who are stricken each year with leukemia, Aplastic Anemia or other blood diseases. For many, the only hope of survival is a marrow transplant from an unrelated donor.

Why unrelated donors?

Of the thousands who could benefit from a marrow transplant, 70 percent cannot find a suitable match within their families. These patients need to find unrelated donors – people willing to come to the assistance of someone they likely will never meet.

Is race a factor?

Leukemia is an equal opportunity disease – it affects all races equally. However, more complicated than matching blood types for a transfusion, marrow transplants require matching tissue types, which are characterized by complex genetic traits often unique to a particular race. So in most cases, an African American will only match another African American.

What is the National Marrow Donor Program?

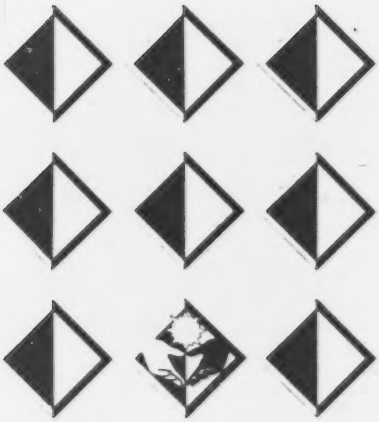
The National Marrow Donor Program maintains a computerized data bank of available tissue-typed marrow donors nationwide. However, to date, 95-98 percent of the bank is made up of Caucasians. Therefore, marrow transplants aren't yet an option for many minorities.

What can you do?

You can help. By registering to become a marrow donor, you can help balance the national registry so that all races are represented equally. So that when African Americans are diagnosed with a life-threatening blood disease, they can receive the "living gift of life."

THE LIVING GIFT OF LIFE

Becoming a Marrow Donor



NATIONAL MARROW DONOR PROGRAM

100 South Robert Street
St. Paul, MN 55107

1-800-654-1247

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DOW

JOINING DONORS AND RECIPIENTS

What is the National Marrow Donor Program (NMDP)?

To meet the need of the thousands waiting for marrow transplants, the NMDP maintains a computerized data bank of available tissue-typed marrow donors nationwide. Established in 1987 as a collaborative effort of the American Association of Blood Banks, the American Red Cross and the Council of Community Blood Centers, the non-profit NMDP enables the efficient sharing and searching of information to join possible donors with patients in need of marrow transplants. The NMDP operates under a contract with the National Heart, Lung and Blood Institute of the National Institutes of Health.

What are the odds of a successful transplant?

While a number of factors influence the success of each individual case, replacing diseased marrow with new, healthy marrow increases the odds of long-term survival from less than 20 percent to between 45 and 80 percent.

THE DONATION PROCEDURE

How are donors and recipients matched?

Matching donors and recipients is a multi-step process. First, a blood test is performed to identify a person's Human Leukocyte Antigen (HLA) type or "tissue type." Once the HLA-type is known, this information is then entered and maintained in the NMDP data bank. When a data bank search identifies a match, the individual is contacted for additional tests and to make a final decision about becoming a marrow donor.

Can you change your mind about becoming a donor?

The answer is yes—potential donors have the *legal* right to withdraw at any time. However, once a match has been made and the patient has started the radiation or chemotherapy treatment required for the marrow transplant, there is no turning back. At that point, there is a moral obligation to proceed, as the patient would almost certainly die without the transplant.

How is the marrow removed?

Marrow, a jelly-like tissue, is collected during a hospital procedure which is performed under general or spinal anesthesia. The procedure generally lasts about 45 minutes. Using a needle and syringe, approximately three to five percent of the donor's marrow is extracted from the pelvic bones at both sides of the lower back area. Typically, an overnight hospital stay is advised. Within two to three weeks, the donor's body naturally replaces the donated marrow.

Does it hurt?

Donors typically experience discomfort and tenderness for a day or two. While it varies from person to person, most donors are back to their usual routines after a few days.

What are the risks?

To date, no donors have experienced any long-term adverse effects; yet, as in any medical procedure, a certain amount of risk exists, primarily associated with the anesthesia. However, the risk is very low.

Who pays for the procedure?

All costs associated with the marrow donation are charged to the recipient or the recipient's insurance company. Some donor costs, such as the initial HLA-typing, child care or loss of salary during the marrow donation procedure and recovery period may not be covered.

When does the patient receive the donor's marrow?

After the marrow is collected, it is immediately transported to the patient's hospital. Depending upon the circumstances, the patient will either receive the marrow immediately or after it has been processed to better prepare it for transplantation. The patient receives the marrow transplant intravenously, in a procedure similar to a blood transfusion. During the transplant, the patient experiences virtually no pain.

Do donors and recipients ever meet face-to-face?

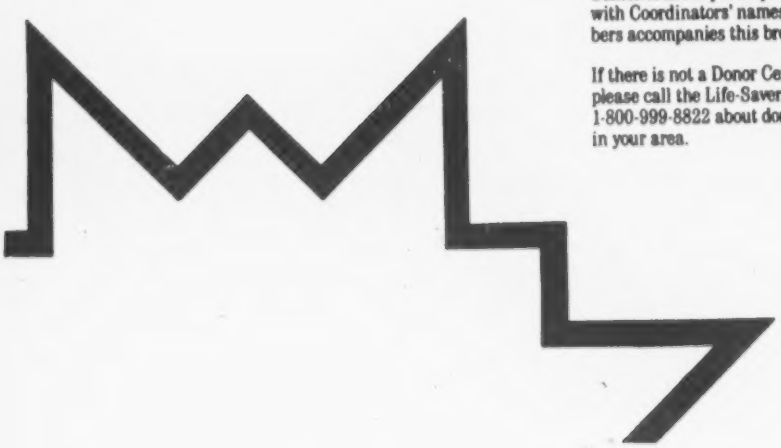
Generally, donors do not meet their marrow recipients. Donors are told about the recipient's condition at the time they agree to donate and are welcome to contact the Coordinator for updates on the patient's progress. After the recipient has been discharged from the hospital, if both parties independently wish to communicate, the donor and transplant centers can help coordinate arrangements.

EXT STEPS

One more question... Why donate? This can be answered only by each individual. There is no monetary reward, no plaque or medal. There simply is the personal satisfaction of giving another human being the living gift of life.

For additional information about registering to become an unrelated marrow donor, please call the Coordinator at the nearest Donor Center. A list of participating Donor Centers with Coordinators' names and phone numbers accompanies this brochure.

If there is not a Donor Center in your state, please call the Life-Savers Foundation at 1-800-999-8822 about donor participation in your area.



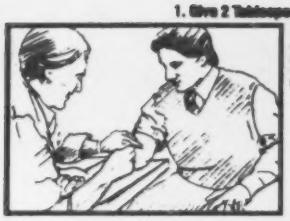
An estimated 16,000 children and adults are stricken each year with leukemia, aplastic anemia or other blood-related diseases. For many, the only hope for survival is a marrow transplant. ◇ Of the thousands who could benefit from a marrow transplant, nearly 70 percent cannot find a suitable match within their families. These patients need to find unrelated donors—people willing to come to the assistance of someone they likely will never meet. ◇ As the pool of potential marrow donors increases, so do the odds of survival for the thousands of patients in need. There is about a one in 20,000 chance of finding a matching unrelated donor in the general population. Since tissue types are inherited, and different tissue types are found in different ethnic groups, the chances of finding an unrelated donor vary according to the patient's ethnic background. A file of 100,000 potential donors, including Caucasians, African-Americans, Hispanics, Asians and Native Americans, would meet the needs of 80 to 85 percent of the patients who need a marrow transplant. Clearly, hundreds, perhaps thousands of lives could be saved if more people added their names to the list of potential marrow donors. ◇ The requirements to be a marrow donor are few. Unrelated marrow donors must be between 18 and 55 years of age and be able to pass a thorough physical examination. No special diet or physical program is necessary. ◇Following are answers to commonly asked questions about marrow donation and transplants.

NATIONAL MARROW DONOR PROGRAM

Attachment XII

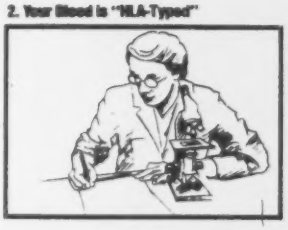
How Do I Become a Marrow Donor?

1. Give 2 Tablespoons of Blood



and consent to be entered on the registry. (Must be 18-55 and in good health.)

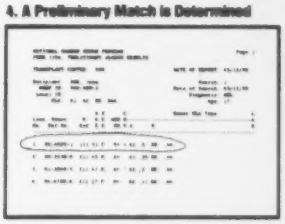
2. Your Blood is "HLA-Typed"



3. Your HLA-Type Goes in the Computer

The ink results are stored in a main computer which is searched internationally.

4. A Preliminary Match is Determined



5. Additional Blood Tests Are Requested

Additional blood samples will be taken to determine if you are a precise match for a specific patient in need.

6. The "Miracle Match" is Identified

Special counselors will give you detailed information.

7. You Make the Decision to Donate

After being fully informed, you make the decision.

NATIONAL MARROW DONOR PROGRAM

100 S. Robert Street, St. Paul, MN 55107

For more information call 1-800-654-1247

The CHAIRMAN. Let me ask, just on this last point, what are the kinds of real concerns that donors have? What is it? Is it a psychological kind of thing? What is it?

Dr. GRAVES. Well, a donor undergoes general anesthesia, Senator. This is termed, in many cases, a life-threatening procedure. A donor has a spouse maybe that isn't too happy about this whole show, or a parent or whatever. We have great concern that the donors that get into the system stay with us. The donors that leave the system at the last moment, as was very dramatically put together on one of our TV networks where a donor backed out at the last minute, we feel is very serious.

However, we respect their right to leave at any time. If they don't want to go to the OR at that point in time, I guess that's correct.

The CHAIRMAN. Do you ever have any that do more than one?

Dr. GRAVES. We have a policy within the national program to not do two. This is under public response and is in the public forum. In many cases, I think it could work. But as a policy, no.

The CHAIRMAN. Let me just say I am familiar with the Hutchinson Center. I had the great honor to be out there at the dedication with Warren Magnuson and had a chance to spend some time going through it and have followed the work of the center over a long period of time and know of its excellence. And we hope you will give our best to the Admiral.

Dr. GRAVES. Thank you.

The CHAIRMAN. We are hopeful that as we are trying to work through some of these areas that have been raised by members today, that maybe from your own insight and working through this you might have some suggestions for us as to how to do it.

Dr. GRAVES. Thank you.

The CHAIRMAN. I know you are accompanied by the doctor. You have heard some of these points that have been raised during the course, and if you would like to make a submission, we will keep the record open for whatever information you may have.

Dr. GRAVES. Thank you.

The CHAIRMAN. I just had a couple of questions.

What is the average time that a seeker looks for a match? What is the average time, do you find?

Ms. KELLER. The patient's overall time? May I? I need to apologize to Congressman Young, and I think I get upset when I find out there are patients out there that didn't know about us. Congressman Young did not confirm that the American Registry was not searched. We know that we confirmed that, Joann Raymond did, that those patients are not on the search file. And we did not—how did I put it? It was not asked the question per se. We asked him if he would take the information back to the patients so that they could access. So I do apologize to Congressman Young.

The CHAIRMAN. We want to note that the good Congressman is still at the hearing. We have Congressmen and Senators come and go at these hearings, but we want to pay tribute for his obviously continuing interest.

Ms. KELLER. And if you don't mind, a patient question, I would rather defer to the director.

The CHAIRMAN. Yes. Fine.

Please?

Ms. Raymond. The question was time involved in the search process?

The CHAIRMAN. Yes. What is the average?

Ms. Raymond. It's not an actual average time. About four to five months to really get a general reading on whether or not we're going to find something for a patient. But we have some patients that are searching for years and then locate a donor. It will depend on the disease. If the patient is to be diagnosed——

The CHAIRMAN. Bring the mike just a little closer, if you would.

Ms. Raymond. A newly diagnosed CML patient has several years, sometimes, to find a donor. But mostly within four to five months we have an idea.

I would like to make a comment, Senator. I run the patient coordinating center. I was one of those motivated moms out there three years ago, and I lost my child also. It's my job to find every option there is for every patient that comes in that door, every donor. So I would dearly love your continued assistance with some cooperative effort with these registries that are out there now.

The CHAIRMAN. Good.

Ms. Raymond. I think we need it desperately. I really do see children dying every month because they haven't been accessed, and it's unnecessary.

The CHAIRMAN. Well, if you would be good enough to help us work with the staff, I say to the good Congressman as well, work with us about how that best can be done. As I say, it is something which is enormously important.

Let me ask you, since names are coming on the registries, maybe daily or weekly, how does that work? How current is the search in terms of those that are being added to the list?

Ms. Raymond. New donors coming into the system, you mean?

The CHAIRMAN. Yes.

Ms. Raymond. The American Registry searches every patient against every donor in the system on a regular basis. So if we have 1,000 new donors this week, they will all be checked against every patient that is still current.

Now, we can't do it with the Europeans. What we do do is run the search again in 6 months for a patient who is still active, and particularly if we've got new donor sources in Europe—and that has happened over the past few years—that will be less likely to happen now. But the American Registry donors are updated.

Ms. KELLER. May I add one comment?

The CHAIRMAN. Yes.

Ms. KELLER. One thing that possibly should be mentioned, we have added the Johnson family after it was a little bit larger than has been stated. We have added 3,000 donors that were recruited because of the Joanne Johnson effort. And the donor drive, for instance, that was done, the three drives by the Green effort, the Jocelyn effort, in the last week, those donors are today being put into the system. And by Monday or Friday, when Joanne gets back, all those donors will have been updated against every patient who is in the files.

The CHAIRMAN. What is the relationship with these various centers, the transplant centers? How do you relate with them?

Ms. Raymond. The relationship between the centers and the American Registry?

The CHAIRMAN. Yes.

Ms. Raymond. Fine. We get requests from the transplant centers all the time. We send patients, donors to the transplant centers.

The CHAIRMAN. And so you have a good working relationship with them?

Ms. Raymond. Yes.

The CHAIRMAN. OK.

Ms. KELLER. Maybe I could add a little bit to that. We work almost daily with transplant coordinators and work back and forth doing testing. We have five MLC's, third-level testing done right now, and four out of those five are for national marrow donor centers.

Senator KASSEBAUM. One thing, Ms. Keller, that I was interested in, your commenting on the criteria for donor matches and that they might differ among transplant centers. I had assumed there was a standard criteria that pretty much had to be met.

Ms. KELLER. There are some centers that—and that criteria probably a national program should be able to give you—but some transplant centers will accept only perfect matches for a patient in order to do transplant. Others may do T-cell depletion, etc., and they may accept less than perfect or minor mismatch at an A or B locus or what have you. Some will accept, as someone mentioned earlier, even a four-out-of-six match for a patient because their protocol and their treatment of the marrow, etc., allows that to be done.

Senator KASSEBAUM. Well, Dr. Lenfant, I would like to ask you, would it be important for criteria to be similar for a similar transplant?

Dr. LENFANT. Yes. Yes, I think it's very important to establish criteria which can be uniformly applied. One of the problems that has existed with the separation between the national program and the American Registry is that common criteria for donors and transplantation haven't been developed, and we feel very strongly that we have to do that, and we agree certainly in part, perhaps not completely but certainly in part, with what has been said here by the American Registry that we have to work to come up with criteria which makes that thing more accessible to all parties.

Senator KASSEBAUM. I would think that that would be something that the medical community itself would want.

Dr. LENFANT. You may have seen, Senator, in my testimony I indicate that we are going to create a policy committee within the institute made up of experts from the country, the best minds we can find, and we intend to work with them to be sure that we achieve this commonality and uniformity which we think is so important.

Senator KASSEBAUM. Ms. Keller and Dr. Graves, you both heard the number of comments, particularly by the first congressional panel, about the need for coordination. We don't coordinate here as much as we should, and it is frequently difficult. But it seems to me that when the goals are very much the same and we so much need to pool the limited resources we have, I find it hard to understand why there isn't a greater effort to coordinate.

Ms. KELLER. There is one major difference, and our donors are even very conscious of the fact. The donors in the American Registry are available to all patients. The donors in the National Marrow Donor Program are limited to participating in only being donors and the participating centers, transplant centers, of the national program.

That means that patients who are on Medicaid and, for instance, in Louisiana, which is the best example I can give, where a young Mexican child whom we just provided a donor to in South Texas, the child was on Medicaid, the parents had nothing. They were doing garage sales to raise money, whatever, to pay this child's medical expenses. He could not even access national because the family definitely could not afford to leave the area where he was to go for transplant. They had no money to pay for transplant. And yet locally he was able to have the transplant done.

A donor was found in the Florida branch. The donor was even willing to go to the facility where the child was for even more cost containment so that there wouldn't have to be a harvest fee paid elsewhere. And the child is eight weeks out of transplant and doing extremely well. His older brother had died with a brain tumor about a month before this child was diagnosed. So it was a whole long story.

But my patients in Louisiana—I say my because they become very personal—there are about 30-plus who are on Medicaid. We have three well-recognized transplant centers in the State, and Louisiana will pay for these kids to have a transplant in the State of Louisiana. If they can't find a donor in the American Registry, the only donor they can find is in the national program. They cannot have a transplant.

First of all, they would have to leave the State and choose a national marrow donor participating center to go to for transplant. That means they lose Medicaid coverage from the State of Louisiana. They now have to live out of their State for 4 months, which is another nonmedical financial cost that is related to transplant. And they can't do it.

Now, we have had it happen and we've had our transplanters call national to see whether this donor could be harvested at a national marrow participating center and the marrow shipped to the patient. And that cannot be done.

Now, that donor does not know that he or she is a match for a 14-year-old boy in New Orleans and is being denied even the knowledge that that donor could save that child's life.

And I am a donor, and I personally don't want somebody coming and telling me you've got to give in one of the national marrow participating centers because we're not going to even let you know if you match a child at Louisiana State or Baylor or West Virginia or Scripps in California or whatever else. You know, I want to make up my own mind.

We provide, we know that some of the centers are not participating centers. In fact, most of our donors have been donors for national program patients. But even if they're not, we tell the donor where the center is that the patient is being treated, we put them in touch with our own medical advisory board, we get them all the information we can on the center where their patient is, on the dis-

ease the patient has, the status they are in, what their chances of success are, and then let the donor decide.

Senator KASSEBAUM. Well, given differences there on that particular aspect, it seems to me that there would be ways of significant coordination.

Ms. KELLER. I would hope so.

Senator KASSEBAUM. Given that particular difference, Dr. Graves, do you have a comment?

Dr. GRAVES. Certainly. When the National Marrow Donor Program actually moved from a concept to reality, the original concept was to determine if this was in fact a viable treatment or a viable option. We did not have the number of cases of unrelated marrow transplantation done at the time this program began. An OTA report mentioned that since my daughter had been transplanted, in the intervening seven years there had only been worldwide 100 marrow transplants done between unrelated people.

The reason for the lack of transplantation was, of course, the lack of donors. It's very simple. There was no lack of patients, there was a lack of donors.

When the marrow transplant program started, we started with previously typed precise donors which came from many, many blood centers around the country. These were people that gave platelets. They were already typed. We didn't have the typing expense.

The first two years of the program, we utilized those precise donors and we were successful in doing over 100 transplants essentially in one year with those donors. It became, then, what we felt a very, very viable treatment option.

But some of the misunderstanding that we have with the American Registry came about there because we did require very, very strict criteria of the transplant centers that were allowed to use donors that we had. We did not wish to put a donor in a life-threatening situation for a disease that was already fatal. Why put two people in place, jeopardize two people when one was already in major trouble?

We wanted transplant centers that had what we felt equal physical facilities and equal experience in marrow transplantation. We placed criteria that said that they had to do 25 marrow transplants before they could apply or be part of our system. This was changed last year. Now that we have a viable option, this was changed. A transplant center today has to do less than, I think it's 10, 10 or 15 allogeneic transplants in the past year to qualify.

I will relate to you that the most eminent transplant center in Louisiana, the most eminent transplanter, Dr. Conrad Gumbard, has applied or is applying. He has been talking to the membership committee, is applying for membership in the national program.

We felt these safeguards extremely necessary. Our program is evolving, moving forward. These are some of the problems of evolution that we have.

The CHAIRMAN. Thank you.

Senator KASSEBAUM. Thank you very much.

The CHAIRMAN. Go ahead.

Ms. Raymond. I would like to comment that I agree with Dr. Graves that the National Marrow Donor Program does need to

have transplant center criteria. The problem is not the criteria, the problem is that there is no control over the charges that these transplant centers. So you have one patient who is told that the administrative fee for access to the National Marrow Donor Program at their transplant center is $3,000 to $5,000, payable up front; you have another that the chart, the administrative fee comes in later; you have another that is doubling the DR typing fees to the national program.

To have these many charges out there to patients, personally I am having a problem at my office because a lot of our patients can't get into the national program. I am talking about fully insured for transplant, Blue Cross and Blue Shield master medical, with no coverage for search cost, who are going to a transplant center and told your access fee is $8,000. If you can't pay it, you can't get in. The patient is not told that there is another transplant center with a $50 access fee, another transplant center with no access fee, transplant centers with fees for staying on the files every month.

What the national program has failed to do is control these access points, control the fees at these access points. So you have to go through one of these centers to get in. They have no idea what these centers are charging, and no control. So, yes, you can find a very equitable center to get in, and other places you can't get in at all unless you have $10,000.

Dr. GRAVES. I would be glad to comment on that.

The National Marrow Donor Program is a very multifaceted program. We have not had the ability to assess charges with transplant centers.

The CHAIRMAN. We are getting back to now an old subject here about health insurance and health insurance costs, and I didn't think that that was going to come up in this particular hearing. It seems to come up in all of them.

But we would really like to see if we can't—it's complicated, and we know that it is—but I think all of us would like to try to reduce some of these barriers and make some sense out of these things, get some limitations on research agencies being able to provide the costs for services as well.

So it is complicated, but we are going to spend some time on this, and try to see if we can't be constructive in helping some of the families that are most affected by this.

We want to thank you. It has been a very helpful hearing. I have learned a lot, and we are very grateful to all of the witnesses here.

[Additional statements and material submitted for the record follow:]

PREPARED STATEMENT OF HELLEN GELBAND, SENIOR ASSOCIATE OFFICE OF TECHNOLOGY ASSESSMENT

UNRELATED BONE MARROW TRANSPLANTS IN THE UNITED STATES: POLICY ISSUES FROM A PATIENT PERSPECTIVE

Earlier this year, OTA looked into how patients go about finding an unrelated bone marrow donor in the United States, in particular, the difficulties that may hamper the search or stop it altogether before all options have been exhausted. Congressman Fazio asked us to do this, wanting to know why there didn't seem to be, in his words, "one stop shopping," one place to which patients and their families could go to have all the search mechanisms turned on. To answer this question, we gathered information about the Congressionally-mandated National Marrow Donor Program (NMDP) and the major registries that have remained independent of the NMDP, which are affiliated with the American Registry (AR), and about the centers that perform bone marrow transplants from unrelated donors. Our findings are reported in an OTA Staff Paper, "Unrelated Bone Marrow Transplants in the United States: Policy Issues from a Patient Perspective."

We found that, particularly for patients whose searches are being conducted through the NMDP, the strategy for searching the available registries and the cost of the search procedure may vary greatly. The variation arises almost entirely from differing practices of the individual transplant centers. The NMDP initiates searches in its own and in unlinked foreign registries at the request of NMDP-approved transplant centers, in accordance with the centers' specifications. Some centers have a sequential approach, searching the NMDP files of about 80,000 potential donors first, and if a match is not found, then going on to the available foreign registries; others request simultaneous searches of various registries. The NMDP does not have a link to the American Registry and does not refer transplant centers to the AR for searching.

The American Registry initiates simultaneous searches of its files of about 28,000 potential donors and its foreign, linked registries, and initiates searches in the three largest unlinked foreign registries; it provides applications for searching three smaller unlinked foreign registries. The AR provides this service at the request of a patient's attending physician, either before or after a patient is referred to a particular transplant center. The AR does not require that transplants from its donors be done at particular centers.

Most potential donors in both the NMDP and the AR are HLA-typed for four of the six loci important for matching donor and recipient, so initial searches are based on those four, the two A and two B loci. All A,B-matched individuals are then contacted and scheduled for blood drawing so that HLA typing may be completed by analyzing the DR loci. This process of contacting, scheduling and DR typing the potential matches may take a month or more. The NMDP and AR arrange for the DR-typing and report the results to the requesting physician. The NMDP charges the transplant centers for these services and the AR bills the patients directly or through a transplant center. The transplant centers are not involved in the search procedure, so these charges, except for administrative costs associated with the paperwork, are largely passthroughs. The AR specifies that no administrative charges be added to their charges, but the NMDP does not. OTA gathered cost information from only a few NMDP-approved transplant centers, but among those few there were large variations in add-on costs, ranging from a modest administrative fee up to 40 percent over what the NMDP charges the centers. NMDP charges to transplant centers for a successful search average $16,000 to $20,000, so the difference can be substantial. The AR charges for corresponding services are at least $5,000 less. In most cases, medical insurance covers the costs of the transplant itself, including the patient costs and usually the costs of harvesting marrow from the donor, but search and DR-typing costs are not covered routinely, and must be paid for by patients directly.

The means by which potential donors are recruited to the registries may also affect patients seeking transplants in cases where no match is found in the registries searched. The registries incorporated into the NMDP and the independent registries historically recruited potential donors in hopes of finding a match for a particular person. But when the NMDP began, it intended to add potential donors by enrolling platelet and plasma donors, who already had been HLA typed, thereby saving the considerable cost of typing large numbers of people. That has not worked. The alternate strategy of recruiting potential donors through blood centers around the country has fallen short of what it might achieve, at least in part because there are no NMDP funds earmarked for typing costs. Large numbers of people have been added to the registry from patient-specific donor drives, however. These drives are funded to some extent by patients' families, but mainly through fund raising in communities. These drives place psychological demands on families, and may create insupportably high expectations that a donor will be found for the patient in question, when the likelihood of that happening is actually low.

The answer to Mr. Fazio's question is that patients looking for an unrelated bone marrow donor do not have "one-stop shopping," and for patients whose searches are being conducted through the NMDP, experiences may be extremely variable, depending largely on their transplant center. In addition, the system is slow and the wait for DR-typing may eliminate many patients with acute leukemias from finding an unrelated donor in time for a transplant.

David and Pamela Cunningham
41 Brookside Rd.
Braintree, Massachusetts 02184
(617) 849-1194

The Honorable Edward M. Kennedy
Room 315
Russell Building
Washington D. C. 20510

Dear Senator Kennedy,

Although I have written to you many times during your years of service to the citizens of Massachusetts and to the Nation as a whole, none of my previous letters addressed issues as important to me as the ones I shall describe below.

My wife, Pamela, who is 31 years old, was diagnosed with a form of leukemia known as Chronic Mylogenous Leukemia (CML) almost a year ago. The initial shock and dismay associated with such a blow were devastating. We have moved beyond that now and, together with her doctors, we are attempting to locate a compatible, non-related bone marrow donor. A Bone Marrow Transplant is the only hope for a cure for Pam's illness.

Pam requires a non-related donor because no one in her family is a compatible match. We are dependent on a successful search of the various bone marrow registries, one of which is operated and administered by the National Marrow Donor Program (NMDP). Fortunately our medical insurance covers the entire cost of this search and the transplant which total approximately $250,000.

Unfortunately, like all other Americans facing the same situation, we must rely on a fragmented system of private registries, including the fledgling NMDP. Currently the National Registry contains approximately 85,000 potential donors. Although the number has increased tremendously recently thanks to several privately sponsored drives, the odds of anyone finding a match through the registry are very slim.

The pool of potential donors must expand. The problem is that no great push for expansion is being conducted at the National level. The job of educating, recruiting, and testing

donors is being undertaken at the local level by friends and family of patients and by non-profit agencies such as the American Red Cross and Life Savers Foundation of America. In addition to the emotional struggle, families are forced to incur a tremendous financial burden in desperate searches for a life-saving donor. While the efforts have resulted in commendable gains in a short amount of time, they are insufficient to meet the needs of most people in need of a Bone Marrow Transplant.

The Federal government can and should do more to educate, recruit, and test potential donors. Studies indicate that a registry of 250,000 would provide a more solid base, thereby offering more hope for Pam and others like her. The initial infusion of funds required to recruit and test enough people is estimated to be less than $15 million.

Pam and I were very disappointed to learn that Congress has failed to appropriate any funding for aggressive enhancements to the NMDP since its creation in 1987. We urge you to take whatever steps are necessary to expand the current base as quickly as possible, to ensure that going forward there is adequate funding to efficiently maintain the registry, and to inform the American public of what it can do to save some one's life. Without active support from the Federal government, expansion could take years.

Pam and nearly 10,000 other Americans currently in need of this life-saving transplant should not have to wait. Sadly, many individuals will die from their cancer befor a donor is found. The American people are willing to help; I hope the American government is also willing to help.

Thank you for your time and your commitment to our cause.

Sincerely,

David E. Cunningham

JOINT PREPARED STATEMENT OF JOHN AND ROSEMARY LINDER

In February, 1988, John started bleeding internally, as evidenced by blood in his urine, stool and phlegm. It was this problem that alerted his doctor to test for leukemia. After three days of tests, including a bone marrow biopsy, and waiting a week we were told John had Chronic Myelogenous Leukemia. This was just one month before John's 39th birthday.

Having taken a gamble (and lost), we were without any health insurance. The only Oncologist in El Dorado refused to see John without advance payment or insurance and would not take Medicaid. We were referred to Dr. Laura Hutchins of the University of Arkansas Medical Center in Little Rock. At our first appointment, we told her that neither one of us were working. She told us that John would probably qualify for SSI and Medicaid and agreed to treat John. We came home and applied for SSI and were accepted; which also gave us Medicaid. Later, he qualified for Social Security Disability and Medicaid 3-month spend-down.

We were able to subsist with the help of our family, church and many friends. John went weekly to the clinic in Little Rock for about 3 months. In June 1988, Dr. Hutchins said we should consider testing all John's two brothers, two sisters, three children and mother for a possible bone marrow transplant. After all testing was finished, in July, 1988, we were told there was no sibling match.

After finding no sibling match, Dr. Hutchins, being familiar with the Fred Hutchinson Cancer Research Center in Seattle, WA, contacted them to start a search for a non-related donor.

In July, 1988 we were told we needed $1,500 cash to send to Fred Hutch in order to find out how many potential donors we had on the National Bone Marrow Registry (NBMR). Since we did not have the money and Medicaid would not pay for the testing of people who were not actually their patients, we turned to family and friends for the money.

In about a week and a half we had raised the money and sent it to Seattle. It then took Fred Hutch two weeks to let us know that we had 82 potential donors (AB matches). In the first half of August we were told to send money to start testing the donors for DR typing. The tests were to be $250 per test. We were asked to send $1,250 to Fred Hutch for at least 5 DR typings. We, again, had to raise more money – it took three weeks this time. By the time we had gathered the $1,250, Fred Hutch informed us that the costs had gone up to $280 per test. We then lacked $200, which we got from a church in our town and sent for the tests.

None of the tests were matches and we were asked to send more money for 5 more tests. However, this time the tests were $340 per test! Not having the money for any more tests, I asked Fred Hutch if there were anything else I could do. It was at this time, when they found out we really were broke financially, that they told me John had 12 AB matches on the Heart of America Registry (HAR) and that they were willing to bill us for the tests. These tests were $125. per test. So, on September 16, 1988, I ordered DR typing on the 12 potential donors on the HAR.

On October 7, 1988, I called Seattle to see if there was any news of the DR typing and was told John had an ABDR match. Fred Hutch was to go ahead with the MLC typing and let us know of the results. Finally, on November 11, 1988, after a month had passed, I called Fred Hutch and was told the ABDR match was a mistake. We were charged for the MLC typing. Since we were still in the same financial situation as before, I asked Lori Hubbard of Fred Hutch, what we should do now. She told me John needed to get on the Anthony Nolan Registry in London, England because their fees were considerably less, $150. per test. To access the Anthony Nolan Registry we needed to send $500 to Seattle as soon as possible. John borrowed $500 from his mother and on November 28, 1988, I sent it to Fred Hutch.

Meanwhile, on September 1, 1988, Arkansas Medicaid approved a plan to cover various transplants; including non-experimental bone marrow transplants. About the same time, I had written a letter to Arkansas Governor Bill Clinton about our need for the transplant. He had his office contact me about the new Medicaid policy and had Roy Jeffus, the Arkansas transplant co-ordinator, contact me about our situation. I soon was able to have

Dr. Hutchins apply for the approval from Medicaid for the medical necessity to have the transplant to save John's life. John was soon approved for Medicaid to pay for the transplant. Arkansas Medicaid was willing to pay 80% up to a ceiling of $150,000. Everything seemed to be on go; except we found out that none of the tests from the Heart of America matched.

A couple of days before Christmas, 1988, we found that John had 52 possible donors on the Anthony Nolan Registry. However, again, we did not have the money for testing any of the donors. Someone sent me an article about Joanne Raymond and her efforts in the Caitlin Raymond International Bone Marrow Registry in Massachusetts. Being desperate, I called Mrs. Raymond and was horrified when I found out that she already knew about my husband and how many potential donors he had from the National Bone Marrow Registry. She informed me that the information about potential donors was free for the asking. It is only after you start testing that you are charged a fee. That fee was $300 not $1,500. The charges for DR testing were $150 per test, not $340. Why then were we charged $1,500 to find out information of which we could have gotten for free? Why did Fred Hutchinson charge $340 per test, having gone up on their fee twice in less than a month form $250? Why?

By January, 1989, we stopped testing altogether because we had no money for more tests. By the end of March, we started more testing through the Caitlin Raymond Registry, because it had access to testing at $150 per test on several different registries. We raised the money for approximately 15 tests. Soon, we were informed that a DR match had been found. However, this match was found on the NBMR because someone else had DR typing done on a donor and did not match. On April 3, 1989, John sent blood to Fred Hutch for MLC testing. I was told by Fred Hutch that it would take 5-6 weeks for the results because there was only one lab in the United States that did this type of testing. I later found out that was not true.

On May 10, 1989 I called Fred Hutch to see if they had any results of the MLC. I was told at that time that, yes, we did have a match. But, the bad news was, that, after verbally accepting Arkansas Medicaid in the fall of 1988, that Fred Hutchinson Cancer

Research Center would not accept Arkansas Medicaid. However, the good news was that they would release the donor information.

After seeing Dr. Hutchins the next week, she told us she received a letter from Fred Hutch about us being turned down for treatment because Arkansas Medicaid could not offer enough money.

On May 16, 1989, I talked with Roy Jeffus, the Arkansas transplant coordinator, and he, too, received a letter form Fred Hutch stating that they would not accept John or Arkansas Medicaid. Feeling that the door was closed at Fred Hutch, Mr. Jeffus decided to try and work with the University of Minnesota. We were eventually turned down by them.

On May 18, 1989, we went back to see Dr. Hutchins and she said a doctor from the Fred Hutch called and was getting ready for John's transplant by having a work-up done on his donor. She told him about the letter. He did not know anything about it. At this point, Dr. Hutchins felt possibly that John sill had a chance at going to Fred Hutch, but for us to not stop looking for another place that would accept John.

Meanwhile, Dr. Hutchins felt Mr. Jeffus and I could do more good than she could in finding a center to accept Arkansas Medicaid. So, we started calling centers across the United States. I called UCLA Med Center on May 22, 1989, and talked to Dr. James Ghaewski about possibly accepting John into their transplant program. He wanted to know why Fred Hutch turned us down. So, he called Fred Hutch and they told him they were still in negotiation with Arkansas Medicaid. That same day, I talked to Mr. Jeffus and he said he had not heard from Fred Hutch since he had received their refusal letter the first week in May. Just with whom were they in negotiations?

Now, Dr. Ghaewaski called me back on May 23, 1989, and said they (UCLA) would not be able to consider John as a patient until Fred Hutch releases him as a patient. He also told me no other center would take John until things were settled with Fred Hutch and they released him or his donor information.

In desperation of what to do next, I called Joanne Raymond of the Caitlin Raymond International Registry in Worcester, Massachusetts. Mrs. Raymond, at that time,

gave me the name of a wonderful woman in Louisiana, who was concerned about people in our situation. On May 25, 1989, I called Joan Keller of the American Bone Marrow Registry in Mandeville, Louisiana. Mrs. Keller then informed me that since the donor came form the National Registry that we may have a problem getting the donor released to a Hospital in Louisiana.

Not beliving everything I hear at this point, I called the National Registry to be sure of this information. On May 30, 1989, I talked to Lori of the National Registry. She told me neither LSU nor Charity in New Orleans were approved to receive marrow from one of their donors. The reason she gave was that the board of the NBMR set up certain criteria that they had not met. That criteria was that the non-related donor program must have been in effect for 2 years and the transplant center must do at least 25 transplants a year. Now, it does not take being a Phi Beta Kappa to know something is wrong because the non-related transplants have only been done for only a year and a half as of May 1989.

Now, armed with this new positive information, John and I saw Dr. Hutchins again and she still felt we possibly, still had a chance with Fred Hutch accepting Arkansas Medicaid. I continued to talk almost daily with Mr. Jeffus who was now in negotiations with Fred Hutch, after they found out we were trying to get into another institution. After much talk with Fred Hutch, they finally reached a figure they would accept from Arkansas Medicaid – $400,000 as the ceiling limit. Needless to say, Arkansas could not go that high and Fred Hutch shut the door on June 7, 1989.

Not being able to have the donor released to an institution that cannot meet NBMR criteria, but to one that accepts Arkansas Medicaid, we are now in the process of starting the donor search all over again. We have a donor! Does he know we can not use him? We have spent thousands of dollars and eleven months of our time. Only thing, this time we will not go through the NBMR. We are going through the American Registry because they will release any donor match to a center of our choice, or as in our case, a center that will accept Arkansas Medicaid.

We are presently working with Arkansas Medicaid to be accepted at Charity

Hospital in New Orleans, Louisiana. We should get an answer this week concerning whether we will be accepted into their transplant program or not. The only problem is, we now do not have a donor and have only about 2 more months on Arkansas' experimental Medicaid transplant program. They are seriously considering stopping the bone marrow transplant program because of all these potential expenses and problems.

Had Fred Hutch told us months ago we would not be accepted or that the NBMR would NOT release the donor to an institution of our choice, then we could possibly already have saved John's life. We were never told by Fred Hutch, at any time, if, for some reason we were not accepted into their program that we would not be able to get the donor information released to another center. Why can not the donor be harvested at an institution of the NBMR's choice and allow us the freedom to choose where we want the transplant done?

I was told by Fred Hutch that the harvesting of the donor would cost between $10,000 and $15,000. They did not tell me that $5,000 of that goes directly to the NBMR for the release of the donor after it has been found. LSU has harvested 2 donors for other centers this year at a cost between $5,000 and $6,000. Why is it so different? The NBMR is subsidized with federal funds to enlist donors. Their consent forms do NOT state anywhere that they are limiting their marrow to only a select group of people at select centers. The donors do NOT know this information and are NOT being told.

I asked Lori at the NBMR about this; she told me that the donors never ask such questions, therefore, that information is not given to them. Just what have we gone back to? CAVEAT EMPTOR! The donors are consenting to be donors, PERIOD! If a donor is willing to give to an unknown patient in Seattle, then is he not willing to give to an unknown patient in Louisiana?

If the United Network for Organ Sharing was formed for equitable fairness among organ recipients, then why is THIS being allowed for the donation of bone marrow? Is bone marrow so different because it is coming from a living being?

How can Fred Hutch say the transplant could be around $400,000, thus putting in jeopardy the Arkansas Medicaid program for bone marrow transplants, when you can fly to

Isreal and get a transplant for $36,000. That is everything – the donor harvesting, transplant, living expenses, flights – EVERYTHING!

The costs of bone marrow transplants should be comparible to other organ transplants. If you weigh the costs of waiting until a patient goes into the acute stage of leukemia, then the care costs could sky rocket higher than the cost of a transplant. If my husband, or anyone else for that matter, can NOT get a transplant, then just what are the costs going to be? The complications of leukemia can be kidney failure, brain tumors, liver disease, etc. The costs of treating these side effects can be as much as the transplant itself. Plus, the patient usually does not recover and dies. The transplant is the gamble that we will be able to contain these costs and allow him to become a productive person again.

By not allowing people to choose where they want to have the transplant done, peoples lives are disrupted. The costs are greater because two living places have to be maintained. In some cases, families are torn apart at a time when they need to be close to home, family and friends. Sometimes the spouse has to stay behind and work in order to keep up the insurance or has other children in school. Some people have to leave their hometowns where they could have had the transplant because the NBMR would not release the donor information to that particular center. In fact, several people have died because they had to start a new donor search after being denied this information. Time to find a donor ran out for these people.

Our daughter was recently offered a job at Burger King. She had to turn it down because is would affect our household income and John would be knocked off Medicaid. I cannot work at this time, more than I do, for it would affect his status on Medicaid. Nowhere could I get a job that John would be accepted on my insurance. I could not make $150,000 by the time he had the transplant. Also, if John dies, could not the benefits his children receive possibly be more than what the transplant costs? The government is subsidizing so much money for AIDS, of which basically the majority got it because of their lifestyle. John did not put himself in any sort of position to contract leukemia, yet our government will allow him to die because there is not enough money or enough regulation in the bone marrow transplant

industry, at this time, to keep the costs within a reasonable limit.

Try waking up daily and checking to see if your spouse, laying next to you, is still breathing or not. It is not a task I would wish upon anybody. This last year and four months of my and my families life has been a living hell. The worst of it is when I really believe it could have been different if some simple changes were made and regulated.

Thank you for inviting us to this hearing and allowing us to air our opinions. We sincerely hope some good will come from this, not just for ourselves, but for other people having similar problems with this system dealing with transplants.

Sincerely,

Rosemary C. Linder
116 Patterson
El Dorado, AR 71730
501-862-3963

The above report was delivered on June 14, 1989 in El Paso, Texas at the Regional Hearings on Cancer in the Poor for the American Cancer Society. After returning from El Paso, Texas, John had an appointment with Dr. Laura Hutchins in Little Rock, Arkansas, June 19, 1989. She informed us that Dr. Deeg from Georgetown University Hospital in Washington, D. C. called about possibly doing John's transplant. We later found out how Dr. Deeg got John's name.

Joan Keller of the Louisiana HLA Registry continued to keep Joanne Raymond abreast of our situation. Joanne Raymond contacted Anita Nita, the transplant coordinator for Georgetown Hospital and explained our need for a hospital with the connections to the National Bone Marrow Registry. Georgetown, being in the National Cancer Institute network, was able to get the donor information and were willing to talk to Arkansas' Medicaid.

On June 21, 1989, Roy Jeffus called and said everything was set and we were to call Dr. Deeg and set up a time to go to Washington for John to have a pre-transplant workup.

Dr. Deeg set it up for us to be in Washington, June 28-30, 1989, for the tests. John apparently passed the tests and we were sent home to wait for the transplant details to be worked out.

During this time the donor coordinator for the NBMR contacts the donor and fully explains the procedure. The donor, after allowing time for careful consideration, is then put through a battery of physical tests he or she must pass in order to donate his marrow. After

the results of the tests are known, the donor coordinator contacts the transplant coordinator with a "go," "no go," or "maybe."

We are presently waiting for this information. We are working getting our life in order to be able to leave for Washington on possibly short notice. John will be an out patient for about two weeks prior to the procedure. His hospital stay will be approximately 4-6 weeks. Upon his release from the hospital, we will remain near the hospital where John will be monitored as an out patient for about 8 weeks.

Hopefully if theings go well, we will be home by Christmas.

The above post script was written before we actually went to Washington for the transplant. John's transplant went very well and showed no signs of rejection. However, do to a severe case of Graft vs. Host disease, he acquired an infection and died December 28, 1989 at the age of 40 leaving a wife and 4 children,that are 16 and under.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Heart, Lung, and
Blood Institute
Bethesda, Maryland 20892

Fax (301) 402-0818

April 27, 1990

The Honorable Edward M. Kennedy
Chairman, Committee on Labor and
Human Resources
United States Senate
Washington, D. C. 20510-6300

Dear Mr. Chairman:

In response to your letter of April 12, I am pleased to send you my responses to Senator Hatch's questions.

Please let me know if you need additional information.

Sincerely yours,

C. Lenfant

Claude Lenfant, M.D.
Director

Enclosure

QUESTIONS FROM SENATOR HATCH
NATIONAL MARROW DONOR PROGRAM HEARING
Held on March 21, 1990

1) Senator Hatch. What do you think can be done to lower the costs of the tests necessary to type the donor?

Dr. Lenfant. There is a short-term and an intermediate- or long-term answer to this question. In the near future, the National Marrow Donor Program (NMDP), under Institute supervision, can competitively award contracts to additional laboratories to perform human leukocyte antigen (HLA) typings in large numbers. The NMDP has successfully done this before, but unfortunately the recent tremendous increase in marrow donor recruitment has overwhelmed the contracting facilities and forced other ad hoc arrangements to be made. It is extremely important to maintain typing quality and, in particular, to obtain typing of sufficient precision to detect the important splits, or sub-types, of the HLA-A and -B antigens.

Current typing techniques are labor-intensive, require live white blood cells (blood samples must be no more than 48-72 hours old), and are not subject to automation. There can be few economies of scale. Molecular or DNA-based techniques can be applied to HLA typing. These procedures do not require fresh specimens, can be automated, and are more precise than those currently in use. The state-of-the-art is nearly ready to apply DNA techniques to HLA-DR typing, which is fortunate, because live-cell HLA-DR typing procedures are less satisfactory than are those for A and B typing. When DNA-based procedures are fully developed, I believe it will be possible to cut DR typing costs in half with these new procedures and to reduce HLA-A and -B typing costs by 30-50 percent. The National Heart, Lung, and Blood Institute (NHLBI) is planning to stimulate research in these new techniques by requesting applications to be funded in FY91.

2) Senator Hatch. What can be done to increase the registered bone marrow donors that are from minority groups?

Dr. Lenfant. The most important barrier to recruiting marrow donors is the cost of HLA typing. This is particularly true of recruiting minority marrow donors. The Institute expects the NMDP will devote about 25 percent of the available federal funds to HLA typing, with special emphasis on minority groups. Considerably more money from charitable donations and from the program's fee-for-service income will be available for HLA typing in general. Even with support available for HLA typing, it will be necessary to educate minority group members to the need for marrow donors and get them to the testing sites. I have provided additional resources to the NHLBI's National Blood Resource Education Program (NBREP) to develop educational materials for minority group members and target them to those most likely to respond. The NBREP commissioned a study of the demographics of African-American blood donors. Since blood donors have been found to be receptive to a request to be marrow donors, the the results of this study will help target appropriate the appropriate subgroups within minorities to obtain the most efficient response.

3) Senator Hatch. What are the barriers to better coordination between the federally supported registry and the private registries?

Dr. Lenfant. There is a certain intransigence on both sides, but we are working toward better coordination. Indeed, there is agreement on several principles, and I will be building on that consensus to bring about better cooperation. 1) All agree that it is important to avoid delays in finding matching donors for potential transplant recipients. The major barrier to sharing all initial searches seems to be providing appropriate resources to the American Registry (AR) to support the additional workload. 2) Both groups accept the need for performance standards, but at issue is how these standards are established and by whom. The Navy contract mandated that the NMDP Board of Directors perform this function. The Institute has been progressively more involved in the establishment of standards and their review and implementation. This will continue. 3) Both groups agree that patient access to the system should be equitable. The principal barriers to access seem to be educational, geographic, and financial. In addition, the donors in the registry(ies) must be racially and ethnically diverse. NMDP efforts are continuing to ensure that all specialists in hematology or oncology know how to access the system for their patients. The NMDP is accessed only through participating marrow transplant units, which are selected after their application is reviewed for compliance with standards. The NHLBI has suggested that preliminary searches be permitted (directly) from any hematologist or oncologist; formal searches would still need to go through participating donor marrow transplant centers. This matter is currently under discussion. There are qualifying transplant centers in many states and in all sections of the country. Transplant centers vary in their initial payment requests, which the AR perceives as a barrier. With our present system of financing medical care, it is hard to see how this could be controlled.

4) Senator Hatch. What is the most efficient way to identify donors and get them into the registry?

Dr. Lenfant. The most efficient procedure for getting donors into the registry is exemplified by the NMDP whole blood donor recruitment program. The procedure is not labor intensive and recruits marrow donors from groups of individuals already committed to altruistic blood donation. Pioneered at the Puget Sound Blood Center with support from the NHLBI, it has been established with an NMDP subsidy at five additional blood centers. The total cost per HLA-A and -B typed donor is about $60 versus $75 in most patient-focused mass recruitment drives. The whole blood donor recruitment program could be rapidly expanded and the Institute will encourage the NMDP to do so. I hasten to add, however, that large, patient-focused recruitment drives are continuing to add many donors to the file. At present, more than half of the donors in the registry have come from such mass recruitment drives, supported heavily by the media.

5) Senator Hatch. What can be done by groups such as LifeSavers to increase the number of organ donors?

Dr. Lenfant. This question has never been explored, to my knowledge. In general, recruiters of altruistic donations have been opposed to approaching "their donors" for other gifts. Blood bankers did not want to approach blood donors to be marrow donors, lest they stop donating blood. This fear has been proven false. Blood bankers opposed sending blood donors fund-raising solicitations for the same reason. Again, the fear was unfounded. I will consider asking such groups to include organ donation literature in their mailings aimed at maintaining the interest and availability of potential marrow donors.

6) Senator Hatch. If a match is not made after contacting the NMDP, what is the responsibility of the NMDP to help the recipient find other registries?

Dr. Lenfant. Since the NMDP does not deal directly with potential transplant recipients, but only through transplant centers, it has been difficult for them to fulfill such a responsibility. Nevertheless, for some time, the transplant centers have had the option of indicating on the search request form that they wish the search to be sent immediately to foreign registries such as the Anthony Nolan in London and the French Registry. Some transplant centers have been accessing these other registries directly. I have directed the NMDP to provide information about the AR whenever a patient calls. The NMDP Access Directory (copy enclosed) carries such information, but this is provided to the patient at the discretion of the transplant center. The Institute is working to find a way that all searches directed to one registry can be promptly referred to the other. The Institute will also try to persuade transplant centers to provide information to potential transplant patients about both registries. It should also be pointed out that each unsuccessful search is automatically repeated by the NMDP each month after the file is updated and the results forwarded immediately to the referring transplant center. This continues until the transplant center cancels the search.

7) Senator Hatch. The OTA report notes that the Board of Directors of NMDP sets policy guidelines and general directives for operation. What is the role of the National Institutes of Health (NIH) in oversight of the management of the NMDP?

Dr. Lenfant. The original Navy contract to the American Red Cross for establishing and running the NMDP gave the Board the responsibility for establishing standards, policies, and procedures. Since the NHLBI took over this contract in February, 1989, we have been playing an increasing role in oversight. The NHLBI project officer attends nearly all of the meetings of the Board, the Executive Committee, and other NMDP committees. The Institute played a role in modifying transplant center standards so that they were more equitable without sacrificing quality. We encouraged the incorporation of a "patient rights" clause in the standards and are now urging better control of compliance among transplant, collection, and donor centers. Believing that it was based on

inadequate and incomplete data, the Institute recently requested that the modification of the donor age standard not be implemented until more information is available to indicate that the change would not adversely affect donor safety. The Institute expects to establish a Policy Committee to advise the NHLBI about the program. This committee will provide an independent review of policies and standards, while eschewing interference with day to day operations.

8) Senator Hatch. The February, 1990 staff report by the Office of Technology Assessment (OTA) states that there is a particular need to recruit enough ethnic minorities to ensure matches for minority populations. What, if any, steps are being taken to increase the number of minority donors?

Dr. Lenfant. The most important barrier to recruiting marrow donors is the cost of HLA typing. This is particularly true of recruiting minority marrow donors. The Institute expects the NMDP will devote about 25 percent of the available Federal funds to HLA typing, with special emphasis on minority groups. Considerably more money from charitable donations and from the program's fee-for-service income will be available for HLA typing in general. Even with support available for HLA typing, it will be necessary to educate minority group members to the need for marrow donors and get them to the testing sites. I have provided additional resources to the NHLBI's NBREP to develop educational materials for minority group members and target them to those most likely to respond. The NBREP commissioned a study of the demographics of African-American blood donors. Since blood donors have been found to be receptive to a request to be marrow donors, the results of this study will help target appropriate the appropriate subgroups within minorities to obtain the most efficient response.

9) Senator Hatch. What, if any, efforts are being undertaken to increase the number of approved transplant centers?

Dr. Lenfant. Of the many physical, educational, and performance standards applied to transplant centers, none was more controversial than the requirement that a unit perform at least 25 allogeneic transplants a year for two years. Considerable and continuing experience is necessary for a unit to manage graft-versus-host (GvH) disease well. GvH, a problem with allogeneic transplants from related donors, is a very severe problem when the allogeneic donor is unrelated. However, it was found that relatively few transplant centers in the U.S. could meet the number standard and that no pediatric centers were that large. During an Institute-encouraged review, it was recognized that the issue was competence and experience in managing GvH disease, as well as the rest of the transplant process. New data indicated that experience with 10 allogeneic transplants each year for two years and a total experience of 30 allogeneic transplants would be sufficient to demonstrate competence and commitment to allogeneic transplants. Patient results would likely be satisfactory and an altruistic marrow donation would not be in vain.

Currently, I believe any center with a commitment to allogeneic transplants could qualify. Many more are now participating, and new ones are being added nearly every month.

10) Senator Hatch. Under current practice, the NMDP approves the transplant centers that they will allow to search their registry and perform transplants from NMDP donors. Wouldn't it be more appropriate for NIH rather than the NMDP to handle the approval process, at least where federal dollars are involved?

Dr. Lenfant. The original Navy contract to the American Red Cross for establishing and running the NMDP gave the Board the responsibility for establishing standards, policies, and procedures. Whereas it is appropriate for the NHLBI to exercise oversight of this, as well as all other parts of the program, it would be difficult for the Institute to perform inspection and accreditation functions. I believe it to be better for the program to continue to function in the same general way it has in the past, but with increased oversight from the Institute and from the Policy Committee that I will soon appoint. One should not forget the very substantial accomplishments of the NMDP since its inception in July, 1986. The standards, policies, and procedures have been modified since the Institute became responsible for the program in February, 1989.

11) Senator Hatch. The OTA report states that transplant center policies on searching the NMDP donor registry vary considerably. Should NIH institute uniform procedures or guidelines in this regard? Or should the NIH persuade the private registries into standardizing their procedures?

Dr. Lenfant. With the present U.S. medical care system, the NHLBI has little managerial control over the fiscal and matching policies of individual transplant centers. For practical purposes, no NHLBI contract money goes to their support. We are told that few insurance companies cover the search process itself, which can be open-ended and cost thousands of dollars in DR typing costs. Transplant centers take various measures to protect themselves against bad debts incurred during the search. Providing insurance against loss would be one way to enforce standard policies, but the NHLBI is not in a position to do this. Persuading both transplant centers and the private registries is possible and stands a good chance of helping. We will try this approach. We will also encourage the NMDP to work with insurance companies to cover the search portion of the marrow transplant procedure more satisfactorily.

12) Senator Hatch. The OTA report also states the NMDP transplant centers set their own criteria for the degree of HLA match they require for a transplant. Do you favor standardization of these criteria either by the NIH or the NMDP?

Dr. Lenfant. The data supporting a requirement for a six antigen match rather than a five antigen match and one minor mismatch are very limited. There are few contemporarily controlled trials supporting various procedures for avoiding GvH disease. It would be difficult to

standardize procedures or criteria without a firm scientific basis. The Institute will insist that changes in the standards, policies, and procedures be supported by reasonable scientific data. We will encourage controlled trials to develop data on which good decisions can be based. The NHLBI is beginning this process by stimulating research on primitive stem cells, which are responsible for engraftment, and on HLA typing, including the degree of match necessary for best results. Science will provide its own standardization.

13) Senator Hatch. We have learned that the NMDP will not allow a transplant, using a donor they identify, to take place at any but an NMDP-approved center. Thus, there have been cases where patients who have found a match acceptable to an unapproved center have been unable to secure marrow. Isn't this an unnecessary bureaucratic hurdle to a patient whose life may be in danger?

Dr. Lenfant. Criteria for transplant centers to participate in the NMDP were developed to protect patients and donors. Patients, and often their physicians, have little or no means of determining the competency of a transplant center. There are three degrees of difficulty in marrow transplantation, governed largely by the frequency and severity of GvH disease. Autologous marrow transplantation, while not simple, is the least taxing. Most new centers start out this way. Allogeneic transplants with related donors are next; GvH is a serious complication with considerable morbidity and mortality. It is worse when the related donor is not an exact match. With allogeneic transplants from unrelated donors, GvH is more frequent and more severe. Managing it taxes even the most experienced unit. The current criteria for transplants centers are such that any transplant center with appropriate resources and competence in regard to allogeneic marrow transplantation can qualify.

Making a marrow donation is not an innocuous procedure for a donor. General or spinal anesthesia is required and most donors spend 1-3 days in the hospital. They must predeposit several pints of blood for autologous use during or after the procedure. For them to make a donation for a hopeless patient in extremis who has no chance of survival, for a mismatch great enough to ensure severe GvH and limit survival, or for a transplant in an inexperienced transplant unit, would be inappropriate. The unwritten pact between the donor and the NMDP is that his donation will be used wisely. Hence, the requirement that a transplant center be qualified is not "an unnecessary bureaucratic hurdle," but rather an important protection for both patient and donor.

14) Senator Hatch. The same criticism could be made of a situation in which it is not feasible for a patient and/or family to travel to an NMDP-approved transplant center for a transplant. We heard about a case in Texas in which a six-antigen match had been found in the database of an NMDP-approved transplant center for a child with aplastic anemia. The family preferred to have the child treated at a university medical center in Texas rather than at an NMDP-approved center that was inconvenient to them. Yet they learned that the NMDP center that has the match will not

contact the potential donor for DR typing until the child is enrolled in an NMDP approved transplant center. Can't something be done to facilitate treatment at a more convenient site in cases like this one?

Dr. Lenfant. I also have heard this story, but find it very difficult to comment without more specifics. There is an NMDP-approved transplant center in San Antonio, Texas. At present there are no others in that state. However, to my knowledge no Texas transplant unit has made application and not been approved since the NMDP became the responsibility of the NHLBI. I don't believe it appropriate to ask a donor to make a marrow donation unless the competency of the transplant center is known to be adequate. Furthermore, patients often assume, to their later regret, that any medical facility that is allowed to operate is competent to perform all of the procedures they do. In the future, the Institute will investigate the specific details of any similar cases and assist in obtaining the necessary treatment without compromising the safety of the donor or the patient.

15) Senator Hatch. Some say that it would be beneficial to potential transplant recipients if NIH combined all the separate donor registries into a consolidated, single registry. Please comment.

Dr. Lenfant. The chances of finding a matched marrow donor increase with the number of individuals in the files searched. One strategy for finding a donor is to search multiple registries sequentially, approaching the largest, handiest, or most efficient first. This takes time and runs the risk of missing a registry. A better strategy would be to search all available registries immediately, providing an early idea of the likelihood of finding a match. Although this could be done by registries sharing searches with each other, it would be more efficient and effective to have all American donors in a single computer file, easily searched with one request. With rare exceptions, a bone marrow transplant is in no way a medical emergency. Nevertheless, it is important to shorten the time from beginning a search for a donor to receiving the transplant, now an average of 4-5 months.

The NHLBI believes that the American public would be better served by a single registry following one set of policies and procedures. While working toward that goal, the Institute will encourage better cooperation between current registries, such as by sharing searches from the beginning.

16) Senator Hatch. At present, each NMDP transplant center is free to decide how much it will charge for its services. The OTA report found that charges varied widely throughout the 31-center NMDP network. Please comment on the advisability of the NIH's developing guidelines for standardized charges for the same services to the extent feasible, given regional cost differentials.

Dr. Lenfant. Transplant centers probably all have similar total costs, but how they recover them within the current US medical care system is subject to local option. Until and unless there is a change in

the way medical care is financed in America. local options on charges will prevail. With the exception of a few research grants, the NHLBI does not support transplant centers, either through the NMDP contract or through other mechanism. Furthermore, the NIH and the Institute have no regulatory responsibilities or powers, nor should they have any. Hence, there is relatively little that we can do to control transplant center behavior.

Nevertheless, there are a few things that can be done, either by the Institute or by the NMDP contractor. Transplant centers can be encouraged to identify on their bills the NMDP charges; regional blood centers often ask the hospitals they serve to do this. The Institute can work with the NMDP to persuade transplant centers to be more uniform, or at least more open. The NMDP, with the help of the NHLBI where needed, can work with insurance companies to cover much of the cost of the donor search. This search cost and its unpredictability are the principal early financial barriers to a patient entering the system.

17) Senator Hatch. Has the NIH met, or will it in the future meet with private insurance companies to encourage them to consider broader coverage of both transplants and searches for donors? If not, why not?

Dr. Lenfant. The Institute has not met with insurance companies on this issue, but we are aware that the NMDP has been very active in that area. Direct delivery of patient care and its financing have not been part of the NHLBI's mandate. Nevertheless, we stand ready to assist the NMDP with the considerable prestige of the Institute in working with insurance companies, should it be necessary. We are aware that this issue bears greatly on the availability of this form of therapy for blood diseases.

18) Senator Hatch. We have heard that donor centers have inadequate resources to cover the cost of blood typing. Please comment on the feasibility of making federal funds available for this purpose. How much would it cost and would the cost be justified by potential benefits?

Dr. Lenfant. The major barrier for recruiting marrow donors is funding for HLA typing. This barrier not only inhibits donor recruitment, but it also leads to HLA-A and -B typing only, because adding -DR typing doubles the cost. Recalling donors for DR typing is the major factor in the four to five months delay between starting the search and performing the transplant. In order to minimize delays, it is important to perform DR typing with the initial donor sample whenever possible. With a completely HLA-A,-B and DR typed registry, the time frame search request to transplant could possibly be reduced to a more acceptable 1-1 1/2 months.

The current NMDP goal is for 250,000 ethnically diverse donors to be listed in the registry. This goal must be regarded as preliminary, to be modified as more information becomes available about the frequency of various HLA combinations in the American public. To go from the present level of 100,000 to 250,000 donors will cost $11.25 million for HLA-A and -B typing alone. That figure doubles if all new donors are also typed for DR. To DR type all donors in the file who are now only A and B typed would take an additional $8.9 million. Hence, to attain a registry of 250,000 donors, all typed for HLA-A, -B, and -DR would require more than $31 million.

QUESTIONS FROM SENATOR HATCH FOR THE BONE MARROW HEARING

1. What do you think can be done to lower the costs of the tests necessary to type the donor?

As you are probably aware, HLA A,B typing costs range from $200.00 to $350.00 when performed in a hospital, medical school, or research laboratory. The national laboratories which have performed this typing for the marrow donor registry effort have maintained the cost between $50.00 and $55.00 for several years now. I seriously doubt that this cost can be lowered considerably unless the typing technique, itself, can be altered.

A surcharge per test is added by those organizations actively involved in donor recruitment and the amount of the surcharge can markedly affect the cost of testing. The American Bone Marrow Donor Registry charges a total fee of $60.00 per test, while others,e.g., Lifesavers, charge a total fee of $75.00 per test. The surcharge of $10.00 added by The American Registry is used for costs associated with administration, equipment maintenance, donor record entry, etc. and could not be lowered. The $15.00 difference in surcharge allows The American Registry to recruit 5 donors to every 4 recruited by those who charge the $75.00 fee.

2. What can be done to increase the registered bone marrow donors that are from minority groups?

A. Enlisting the aid of respected leaders (religious, medical, media) from minority groups to help with education about the need for and procedure invovled in becoming a marrow donor.

B. Subsidizing the cost of testing among minority populations, until at least enough donors are registered to give the minority patient a chance to find a donor.

3. W[illegible] the barriers to better coordination between the federally supported regist[illegible]d private registries.

A. Communication, understanding and acceptance....
Open communication and acceptance of the fact that a private registry can function efficiently and cost effectively to the benefit of all patients, not in competition with, but as an adjunct to the service provided by the NMDP has been lacking.

B. A more concrete answer would be that the Board of Directors of the NMDP has been the main obstacle to better coordination. Coordination and cooperation, where it matters most, at the transplant center level, has not been a major problem. The American Registry works daily with the BMT coordinators at many participating transplant centers and has supplied many donors to those centers. However, repeated submission of proposed cooperative agreements to the NMDP have gone unanswered; scheduled meetings have been unattended, etc.

4. What is the most efficient way to identify donors and get them into the registry.

There is no one simple answer to this question. Donors are human beings, individuals. It would be impossible to say that there is one particular way to identify donors....some are blood donors, some are relatives of patients who very suddenly become aware of the need for donors, others are individuals who simply respond to the need when they become aware of their ability to help another. Individuals who request information must be sent educational material, have testing scheduled upon receipt of signed consent, and have test results entered in the computer files as quickly as possible. Group drives must be well managed and assure proper donor education, blood samples shipped by prearranged carriers, and test results quickly entered into computer files.

5. What can be done by groups such as Life Savers to increase the numbers of organ donors?

I cannot answer for Life Savers...I can say the The American Registry is trying, by means of publicity through the media, speaking engagements, etc. working to increase the number of marrow donors.

6. If a match in not made after contacting the NMDP, what is the responsibility of the NMDP to help the recipent find other registries.

It is the contention of The American Registry that anyone involved with the process of patient-donor matching has a moral responsibility to help the patient, from day one, find a compatible donor as quickly and efficiently as possible. Certainly, patients in this country should be made aware immediately of all existing options available to their search effort. It is for this reason that The American Registry, upon receipt of a search request, immediately informs the patient by written notification of the existence of and procedure for accessing the NMDP and encourages immediate access. Searches done in incremental stages can seriously alter the outcome for many patients where time is of the essence. On the other hand, it is to the benefit of many patients that their transplant surgeion have a choice of donors and ultimately have the best transplant possible.

7. What is the role of the NIH in oversight of the management of the NMDP?

The defined role of the NIH is not totally clear.....however, it is felt that the NIH should be the umbrella, so to speak, under which not only the NMDP, but other registry efforts operate and interact, perhaps in somewhat the same way as UNOS interacts with private, non-profit organ procurement agencies throughout the country.

8. What, if any, steps are being undertaken to increase the number of potential minority donors?

I can speak only for the American Registry. Major efforts have been made and are continuing to interest and educate minority donors. This has resulted in an increase of several thousand new donors from among the Black and Asian population in this country in the past few months.

9. Not qualified to answer.

10. ....Wouldn't it be more appropriate for NIH rather than NMDP to handle the approval process, at least where federal dollars are involved?

The American Registry agrees with this premise.(see attached) The American Registry has been of the opinion that tranplant center criteria should be the province of the NIH as a federal agency, and not the NMDP.

11. ...Should NIH institute uniform procedures or guidelines in this regard? Or should NIH "jawbone" the private registries into standardizing their procedures.

If NIH is to be the overseer of the NMDP, then it should see that uniform procedures or guidelines with regard to searching the NMDP are established, for the sake of accessing patients. The NMDP in principle is a good program. The basic fee structure of the NMDP itself is warranted and fair.....the problems have arisen because the NMDP does not control the program....the program is controlled by the transplant centers. For example,the patient-donor search is a service of the NMDP; and such a service should require a set fee. The fee established is augmented by individual transplant centers, in some cases, by several thousand dollars. Monthly fees have now been assessed by some centers for updating searches. Patients are seldom aware of options which exist throughout the system and often drop out of the search process. NIH could provide, or see that patient advocacy is provided to guide the patient through the complicated procedure of donor searching.

The American Registry has set procedures, guidelines, and fees. (see attached). A one-time access fee is charged for searches and no additional fee is required for updated reports of new matches sent to physicians as new donors are added to the system. Searches continue until cancelled by the attending physician/transplant center. Set procedures are in place through the MLC level. Once a designated donor has been identified, the American Registry has the flexibility to work within the protocol of the transplant center involved.

12. ....Do you favor standardization of these criteria either by NIH or NMDP?

In a field still as new as marrow transplant, dictating the protocol for each transplant center does not seem advisable. It should, however, be required that patients be advised of other options at alternate transplant centers if they do not meet the requirements of their chosen center, or the donors identified do not meet the protocol of the chosen center.

13. ...Isn't this an unecessary bureaucratic hurdle to a patient whose life may be in danger?

AMEN! In most of these cases, not only does the patient not have access to the donor or marrow, but the donor is not aware of the fact that he/she does indeed match a patient and is being denied the opportunity to give his or her own informed consent to donate. There are two possible solutions:

A. Give the donor the information about the match, the patient's age and condition, chances for survival, the transplant center involved, etc. and allow the donor to give his/her own informed consent to donate.

B. Establish a review panel to look at each case. This could be done through NIH.

In either event, the donor could be harvested at an NMDP participating center and the marrow shipped to the patient's transplant center.

14. ...Can't something be done to facilitate treatment at a more convenient site in cases like this one? (patient preference for TX center)

A simple change in procedure which would not force a patient to choose or commit to a transplant center until a DR match had been identified would alleviate the situation in some instances. The particular family mentioned has been put through a tremendous amount of emotional turmoil, perhaps needlessly. If the DR is not a match, the upset was unnecessary. This does not, however, answer the basic question. Does a program such as the NMDP have the right to remove the choice of a treatment facility from a patient, particularly when such a long term separation from family, support people, etc. is involved? The American Registry works with the patient, patient's physician and donor to arrange the transplant and harvest as conveniently as possible to all parties concerned.

It has been our experience that donors volunteer in order to be able to help any patient whom they might match. Many donors recently have been transferring their files to the American Registry because they have learned that they could match a patient and never be told. These donors have been quite upset. Again, the answer is not duplication of registration, but a solution to the basic problem. How much input should the donor have in the decision to donate or not to donate? Should not these donors be given enough information to allow them to make an informed decision. How big a problem is this question when the donors in question can be harvested at a NMDP participating center?

15. ....? combine all separate donor registries into a consolidated, single registry.

The single registry question is not paramount....what is essential is a single "network" of registries which allows a patient to access the greatest number of donors simultaneously. The American Registry cooperates or interacts with approximately 40 registries in this country and worldwide and is in the process of establishing a total system of electronic intercommunication thanks to the generosity U.S. Sprint. In a country the size of the United States the existence of the two major registries has provided a system of checks and balances for both. Federally funded and privately funded organizations can and do co-exist compatibly in other situations. If both of the existing major registries in this country immediately sent written notification to accessing patients of the existence and access procedures of the other (a practice followed by the American Registry) patients would have immediate access to all known donor sources worldwide. It is disturbing that so many times patients in this country have learned of the American Registry from outside sources too late in the search process to even have a chance.

16. see #11, paragraph #1

17. Insurance
Not familiar enough with the activities of NIH in this matter to comment.

18. Recruitment of an adequate number of donors to provide a chance for transplant to a statistically acceptable number of patients is not a difficult thing to accomplish....except for the cost. It has been the experience of the American Registry that the majority of donors fall into the age category of 24-40 years old. This is the age group which can least afford to budget the $60.00 cost of the HLA typing (house mortgages, car payments, tuition,etc. are primary expenditures). Only 25% of those new donors tested can pay for testing. Although some corporations and businesses pay for employee donor testing,and the donor centers themselves solicit funds, the major part of fund-raising has resulted from the efforts of patients' families and friends. This is the group most anxious to help in the recruitment, but certainly is the group which should not have to deal with the pressures of fund-raising.

Making federal funds available for marrow donor testing would allow the numbers needed for effectively matching patients and donors to be realized much sooner than now projected. It would free the registries from the time consuming work of soliciting funding (although this type of effort should not be totally discontinued). According to recent articles comparing the medical costs of leukemia patients tranplanted versus long term chronic care, statistics clearly indicate the cost effectiveness of the transplant procedure. Because the only way to increase the number of transplants performed will be to increase the number of registered potential donors, it appears that whatever has to be done to speed the registration of new donors would be worthwhile.

Any federal funding made available should be carefully monitored to assure the proper use of the funds for the intentions it is allocated. Perhaps the most effective way to accomplish this would be to establish through competitive bidding a defined cost per test and to allow a set surcharge per test to be paid to the registries according to the numbers typed. The payment for testing done would have to be done on a timely basis in order to allow the registries to keep laboratory accounts current. Participating laboratories would have to be able to type donors anywhere in the country and to report typing results expediently. Registries, on the other hand would have to assure rapid entry of test results for immediate searching. If this project were to be funded with public monies, then some assurance would have to be forthcoming that donors so recruited would be accessible to all patients in need of marrow transplantation.

Respectfully submitted

Joan Keller

Joan Keller M.T.
President
The American Bone Marrow Donor Registry

National Marrow
Donor Program

100 S. Robert Street
St. Paul, MN 55107
1-800-526-7809

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Douglas A. Shaw
Executive Director

May 1, 1990

The Honorable Edward M. Kennedy
United States Senate
315 Russell Office Building
Washington, D.C. 20515-2101

Dear Senator Kennedy:

Enclosed are the National Marrow Donor Program's answers to the 18 questions you forwarded to us from Senator Hatch's office.

In addition to answering specific questions, there are three points I would like to make:

1. The National Marrow Donor Program has been phenomenally successful. Since November, *thousands* of reporters have helped spread the word about our international crusade; *tens of thousands* of Americans have responded to our pleas for help with financial contributions and/or by volunteering for our Registry. This Program has expanded rapidly because of its responsive Board and staff with momentum coming from desperate families and dying patients and a truly indescribable demonstration of human compassion and generosity.

2. While we have research responsibilities, we view our primary mission as one of service. Because of this, we continue to struggle with how to work within the National Institutes of Health system, which is primarily focused on research. After some growing pains, we have great optimism that, with the able help of Dr. Claude Lenfant, Director of the National Heart, Lung, and Blood Institute, a process will be streamlined which allows us to rapidly respond to patients while fulfilling our research and reporting requirements for the federal government.

3. The misleading rhetoric of representatives of the remaining private registries has escalated recently, confusing members of the media, of Congress and the general public and most tragically, patients. There is no room for "turf battles" when the lives of patients are at stake. In spite of these unfortunate distractions, our mission remains focused on:

A collaborative effort of the

American Association of Blood Banks

American Red Cross

Council of Community Blood Centers

With funding from The National Heart, Lung and Blood Institute

- Building a racially and ethnically diverse registry of 250,000 U.S. volunteer donors typed for HLA-A,B and DR;
- Establishing effective working relations with marrow donor registries in other countries so that patients will have access to a million volunteers worldwide; and ,
- Promoting the cooperation of insurance companies and the availability of adequate public funding to assure access to the potential life-saving gift of a stranger for all persons in need of an unrelated donor marrow transplant.

Please feel free to contact me if you have further questions or wish clarification of any of my answers.

Thank you for your interest in this very special Program.

Sincerely yours,

Bob Graves

Robert C. Graves, D.V.M.
Vice Chairman

United States Senate
Committee on Labor and Human Resources

Response to Questions Posed By
The Honorable Orrin G. Hatch

Presented By
Robert C. Graves, D.V.M.
Vice Chairman, Board of Directors

National Marrow Donor Program

May 1, 1990

1. Senator Hatch: What do you think can be done to lower the costs of the tests necessary to type the donor?

Dr. Graves: The cost of HLA typing donors for the National Marrow Donor Program (NMDP) has been and will be further reduced by competitive bid contracting with several laboratories. Assuring these laboratories a high volume of testing will allow NMDP to take advantage of volume discounts without compromising on the quality of the typings.

Researchers are working on new technologies for HLA typing. Eventually these new technologies will make it easier and less expensive to type large volumes of donors. Meanwhile, the NMDP must continue to provide high quality HLA typing at the lowest possible price to patients and their families.

An overall reduction in the cost of HLA typing could be realized if the donors could be completely HLA typed at the time they are initially tested. Currently, newly recruited donors are only HLA-A and B typed because of the lack of funds to completely type them. The cost of HLA-A, B and DR typing a donor is roughly twice the cost of performing the HLA-A and B typing alone. However, having a file of completely typed donors would significantly reduce the time it takes for a patient to locate a matched donor and reduce the financial burden on families.

2. Senator Hatch: What can be done to increase the registered bone marrow donors that are from minority groups?

Dr. Graves: In the Fall of 1989, about two percent of volunteer donors registered with the NMDP were minorities. This basically reflects the percentage of minority blood donors in the U.S. It was from the blood donor community that NMDP first recruited marrow donor volunteers.

In the past year, the percentage of minorities in the NMDP Registry has increased significantly, up from 2% to 6% of the total registry. The growth in minority volunteers has, in fact, accelerated faster than the overall rapid growth of the registry.

However, NMDP has found unique differences and needs for recruitment in specific minority populations and there appears to be less success in raising funds for typing within the minority population.

In 1990-91, NMDP will continue to focus recruitment efforts on minority populations with a goal of further expanding the number and percentage of minority donors in the NMDP Registry. These efforts will require the development of new relationships with minority recruitment organizations as well as expanded programs to reach these special populations through existing NMDP recruitment mechanisms. To assist with this initiatrive, NMDP is working with the NHLBI's National Blood Resource Education Program to develop and disseminate information on the need for minority marrow donors.

NMDP has ear-marked an estimated $800,000 in 1990-91 to develop plans, an expanded structure, and support materials to carry on effective minority recruitment. This is in addition to the special emphasis on minority recruitment with general NMDP donor recruitment funding. In addition, $250,000 has been allocated specifically to offset the cost of HLA typing new minority donors.

(Please see Attachment A, Donor Registry.)

3. Senator Hatch: What are the barriers to better coordination between the federally supported registry and private registries?

Dr. Graves: First, the record needs to be accurate when comparing the NMDP and the remaining private registries. It is not just size which distinguishes these groups (NMDP has over 112,000 volunteer donors who are distinct from the estimated 10,000-15,000 donors enrolled with the private registries).

Performance is the real distinguishing mark. NMDP has facilitated over 345 transplants since the inception of the Program (Fall, 1987) and currently averages an additional transplant each and every working day of the month. In contrast, major transplant centers throughout the country report performing perhaps only 20 *total* transplants facilitated by the remaining private registries in more than four years of operations. As discussed in Question 11, the NMDP is aware of a number of transplant centers which are reticent about approaching the private registry group because of problems with communications, delays in obtaining data reports and general lack of medical planning and supervision for assuring the safety of the donor.

NMDP is committed to achieving a close, collaborative, working relationship with the private registry group. Unquestionably, all patients would best be served if a consolidation of registries is accomplished. We continue efforts and willingness to participate in any constructive discussions which would move toward this goal.

The principal barrier to better coordination has been our failure to resolve some specific philosophical differences in registry procedures. The private registries who remain independent and unaffiliated with the NMDP have been described as "patient advocates." We understand fully this role and have great empathy and sensitivity for desperate families. Indeed, NMDP's Board of Directors includes several members who understand this situation firsthand. Nevertheless, as Fred Harris, who heads Heart of America (previously the largest of the private registries and now an integral participant of NMDP's system), so eloquently states, the protection of the donor's health and welfare must be the *paramount concern* of any registry:

"I happen to be a parent of a child who had leukemia but that is not reason enough to assume that an unrelated donor should face real, life-threatening risks. The donor and his or her family must be provided with guarantees that they are not being asked to do anything unwarranted. All of us understand how desperate parents can be when their child's life is at stake but I cannot think of a greater tragedy than that a donor is put at risk for a patient who has no chance of surviving. That would be the greatest tragedy of all."

(Please see Attachments B and C, Fred Harris letters.)

Recently, the NMDP has initiated efforts which, with the cooperation of the private registry group, will assure that patients seeking donors through either system will be routinely informed of a possible matched donor in the other registry. Additionally, resource materials developed by both organizations now inform patients and referring physicians about alternative registries. While helpful, these measures should be viewed as interim at best.

The American Association of Blood Banks and the Council of Community Blood Centers -- two of NMDP's sponsoring organizations -- recently reaffirmed their respective positions regarding the fundamental obligation of the NMDP (or any other donor registry) to inform, protect and serve donors.

(Please see Attachments D and E, from NMDP's sponsoring organizations.)

Dr. Claude Lenfant, Director of NHLBI, has offered to facilitate discussions between the NMDP and the remaining private registries which function independently of NMDP. We eagerly await the initiation of these discussions.

4. Senator Hatch: What is the most efficient way to identify donors and get them into the registry?

Dr. Graves: Donors are currently recruited through blood centers/participating donor centers and through NMDP recruitment groups such as Life-Savers. These approaches, while usually appealing to different audiences, continue to face obstacles because of lack of funding for HLA typing. Both methods of recruitment are effective when funding is available.

To speed the recruitment, typing and entry of new donors into the central donor registry, the NMDP is instituting an automated, bar-code system. This optical scanning technology will allow electronic transmittal of new donor information directly to the Registry and linkage within the computer of the donor ID and HLA data, assuring that new donors are incorporated as soon as possible into the central registry while at the same time guaranteeing donor confidentiality. This system will allow patients waiting for new donors who may be potential matches to have access to these new donors within days of donor recruitment and the completion of HLA typing.

5. Senator Hatch: What can be done by groups such as Life-Savers to increase the numbers of organ donors?

Dr. Graves: An unrelated solid organ donor must be deceased while marrow is a living gift of life. Because of the confusion that has existed regarding this fact, solid organ donation has not been included in preliminary marrow recruitment literature. However, the NMDP plans to consult with organ donor specialists, perhaps through cooperation with the OPTN to develop a coordinated approach to donor education.

(Please see Attachment F, sample organ donor newsletter.)

6. Senator Hatch: If a match is not made after contacting the NMDP, what is the responsibility of the NMDP to help the recipient find other registries?

Dr. Graves: NMDP works directly on behalf of patients seeking an unrelated donor. In this regard:

•NMDP routinely offers to facilitate a search of foreign registries affiliated through the International Cooperative Marrow Donor Program. NMDP routinely exchanges searches with Canada, France and the United Kingdom. Unfortunately, applications from countries wishing to establish a formal relationship with the NMDP have been held up because of the requirements of the Office of Protection of Research Risks in HHS. While The Netherlands donor center was originally accepted without an extensive application process, Israel's donor center application, which was approved by NMDP as meeting our standards on August 7, 1989, is still pending. If and when this application process is streamlined and as other countries successfully build their registries, we expect an efficient, computerized system for patient searches to evolve on an international basis.

•NMDP is willing to receive preliminary search requests directly from the private registries and to promptly inform them if there is a potential match in the NMDP Registry. This service is available at no cost to the private registries or to the patients.

•NMDP has begun routinely sending preliminary search requests to the private registry group for all searches initiated with the NMDP by participating transplant centers. NMDP will promptly notify the participating transplant center if there is evidence of a potential match. To date, the private registry group has not notified the NMDP of any matched donors in its file.

•NMDP plans to add a patient affairs coordinator to its staff, has expanded its training of NMDP phone operators, and includes the address and phone number of the private registries' search coordinating center in its packets for referring physicians and patients.

However, the optimal solution is an integrated marrow donor registry in the U.S.

7. Senator Hatch: The OTA report notes that the Board of Directors of NMDP sets policy guidelines and general directives for operation. What is the role of the NIH in oversight of the management of the NMDP?

Dr. Graves: In the original Navy contract for the marrow registry, the Board of Directors was mandated to establish standards, policy guidelines, and general directives for operating the program. The Board has carried out these instructions with the help of a number of committees. In addition, open meetings have been held to help develop a consensus on controversial issues. Hence, the Board believes that the current process works well. The NHLBI could easily carry out this oversight function with annual reviews at the time of contract renewal, as well as through informal interactions throughout the year.

8. Senator Hatch: The February 1990 staff report by the Office of Technology Assessment states that there is a particular need to recruit enough ethnic minorities to ensure matches for minority populations. What, if any, steps are being taken to increase the number of potential minority donors?

Dr. Graves: As discussed in Question 2, the NMDP has given increasing emphasis to the recruitment of minority donors. Currently, the NMDP is proposing to focus specifically on three minority groups: African, Asian and Hispanic Americans. Specialized literature, recruitment training sessions and targeted multi-media campaigns are being planned for 1990-91.

9. Senator Hatch: What, if any, efforts are being undertaken to increase the number of approved transplant centers?

Dr. Graves: In October, 1989, the NMDP held an open hearing to discuss transplant center criteria. As a result of this hearing, the criteria for participating transplant centers were revised, thus making more transplant centers around the U.S. eligible for participation. Notices were sent to previously ineligible centers and a number of new centers are applying for membership each month. Because many medical centers are just now getting their transplant team and support services in place, NMDP expects to experience steady growth of participating transplant centers for at least the next three years.

At the current time, 32 U.S. transplant centers have submitted applications and been accepted for membership in the NMDP network.

10. Senator Hatch: Under current practice, the NMDP approves the transplant centers that they will allow to search their registry and perform transplants from NMDP donors. Wouldn't it be more appropriate for NIH rather than NMDP to handle the approval process, at least where federal dollars are involved?

Dr. Graves: The NIH does not now have any accreditation program, nor does this generally fall within its scope of activities. The National Heart, Lung, and Blood Institute is now working with the NMDP as medical standards and policies regarding approval for participating donor, collection, and transplant centers are developed and modified. The Board believes that these standards have been developed through an objective, fair and open process, are equitable and scientifically defensible. Their development and modification using a consensus approach has served the program well. There does not appear to be a need for the NHLBI to become directly involved as an accrediting agency.

11. Senator Hatch: The OTA report states that transplant center policies on searching the NMDP donor registry vary considerably. Should NIH institute uniform procedures or guidelines in this regard? Or should NIH "jawbone" the private registries into standardizing their procedures?

Dr. Graves: NMDP's patient rights standards encourage member transplant centers to turn to other registries, both domestic and foreign, if a compatible donor is not available through the NMDP. Furthermore, transplant centers may, and often do, decide to search multiple registries simultaneously. All NMDP transplant centers know of the existence of the remaining U.S. private registries as do many referring physicians. Contrary to concerns expressed repeatedly by the private registry group, access to information about them and the private registries' search coordinating center is NOT a problem. Rather, many transplant centers report a reluctance to deal with the private registry group. This reluctance stems from their perception that the search process utilized by this group is slow and inefficient; that months may go by before a response to an urgent search request is received; that the anonymity of the patient and donor is threatened because of the lack of clear guidelines for their protection; and even the safety and protection of the donor may be compromised by the procedures employed by the private registry group.

12. Senator Hatch: The OTA report also states that the NMDP transplant centers set their own criteria for the degree of HLA match they require for a transplant. Do you favor standardization of these criteria either by NIH or NMDP?

Dr. Graves: The NMDP has established basic criteria for donor matching which allows a maximum of a one antigen mismatch. Some transplant centers use this option and perform transplants with donors who are mismatched at one antigen; other centers have more conservative match criteria and require complete matching of all six HLA antigens. The degree of match may be an important factor in transplant outcome. However, sufficient data does not exist at this time to draw definitive conclusions. The NMDP is collecting data on the outcome of all transplants and will be

performing an analysis of that data when a sufficient number of transplants have been performed.

In the meantime, patients who do not meet the criteria of one NMDP transplant center can be referred to another participating center. NMDP policies and procedures exist for transfering the patient's file and unrelated donor search record in an expeditious manner. This flexibility is essential to evaluating the relative merits of alternative treatment protocols. For these reasons we do not favor more restrictive standardization of matching criteria at this time.

13. Senator Hatch: NMDP will not allow a transplant using a donor they identify to take place at any but an NMDP-approved center. Thus, there have been cases where patients who have found a match acceptable to an unapproved center have been unable to secure the donor marrow. Isn't this an unnecessary bureaucratic hurdle to a patient whose life may be in danger?

Dr. Graves: The NMDP has a Standards Committee consisting of medical specialists and advocates for both donors and patients which sets standards for transplant centers as well as donor and collection centers. All of the standards of the NMDP are aimed at the goals of protecting the rights and safety of donors and patients. The marrow donation process itself carries with it significant risk to the donor because it involves spinal or general anesthesia. Because of this, it has been the policy of the NMDP to carefully evaluate the programs and outcomes of participating transplant centers in order to ascertain that programs established at those centers will guarantee a reasonable probability of success for patients transplanted at that center. It is unreasonable to potentially jeopardize the health and safety of a donor to provide marrow for a center where transplants may be undertaken with little or no possibility of success. Because patients look to the NMDP as a clearinghouse and guide in the selection of a transplant center, it is critical that the NMDP has objective and fair procedures for assuring medical facilities meet benchmark medical standards.

14. Senator Hatch: The same criticism could be made of a situation in which it is not feasible for a patient and/or family to travel to an NMDP approved transplant center for a transplant. . . Can't something be done to facilitate treatment at a more convenient site in cases like this one?

Dr. Graves: It is regrettable that some patients have to travel great distances to receive certain kinds of specialized medical care. The NMDP will assist all transplant centers seeking membership in the Program. Ultimately it is the responsibility of the local transplant center, hospital and community, to make the kind of program and financial commitments needed to build a qualified marrow transplant team. This requires not only a skilled team of medical and nursing specialists, but also major support and commitment from the institution sponsoring the Program.

To reiterate, NMDP standards and related treatment protocols have been carefully designed to protect the interests of both the donor and the patient. The NMDP and its network of donor centers will only approach a potential donor when requested to do so by an approved transplant center operating in accordance with NMDP policies and procedures. The NMDP system cannot -- and will not -- do anything which might jeopardize the health, safety and anonymity of the volunteer donor.

For the patient, the selection of a treatment center to evaluate the patient's medical condition and perhaps perform a marrow transplant, of necessity, should consider the credentials of a particular center's transplant team and the center's ability to both locate and access possible compatible donors available through the NMDP or other registries.

To preclude the situation of a patient in need not being informed that multiple registries exist, worldwide, that could offer the possibility of a matched donor, the NMDP now routinely forwards any preliminary search requests its receives to the private registry group in the U.S. Patients are also informed and given the option of foreign registries being searched (some foreign registries have or will soon be searched automatically because of their participating status with the NMDP; please see Question 6). This system -- with the cooperation of the various registries involved -- is

as close to "one-stop shopping" as is possible, short of integrating all U.S. registries into a single, united program.

NMDP is aware of transplant centers in the U.S. which meet the criteria of the Program but which have not yet submitted an application for membership. Again, we hope to have *regional* coverage within a few years as more medical centers develop the capability of performing bone marrow transplants using unrelated donors.

15. Senator Hatch: Some say that it would be beneficial to potential transplant recipients if NIH combined all the separate donor registries into a consolidated, single registry. Please comment.

Dr. Graves: With the exception of a few private registries, this has already been done by NMDP to create the current, expanding network of donor centers.

The NMDP utilizes a highly sophisticated computer system to store information on volunteer donor typings and conduct searches for possible compatible donors. This system, for example, allows transplant centers to access a single donor registry containing more than 112,000 donors from 68 different donor centers in the U.S. as well as 190,000 donors in Canada, France and the United Kingdom. Communications are sent to transplant centers electroncially, informing them of possible matched donors within 24 hours of receiving preliminary search requests. Once one or more potential matches have been identified, the NMDP provides coordinating services and monitoring for subsequent requests for additional blood samples for DR typing, donor counseling, physical examinations, marrow collection, etc. The NMDP believes that the public interest would be best served by integrating the remaining 10,000-15,000 *unduplicated* donor typings into the NMDP electronic registry as soon as possible. We are hopeful that, with the assistance of the NHLBI, a consolidation of efforts will occur.

16. Senator Hatch: At present, each NMDP transplant center is free to decide how much it will charge for its services. The OTA report found that charges varied widely throughout the 32-center NMDP network. Please comment on the advisability of NIH's developing guidelines for standardized charges for the same services to the extent feasible, given regional cost differentials.

Dr. Graves: In providing unrelated donor marrow transplants, transplant centers have found it necessary to provide new services never before needed when performing marrow transplants from sibling donors. When services for unrelated donors such as DR typing, physical examinations and marrow harvesting are done on behalf of a patient, the bills are sent to the transplant center initiating the request. Insurance companies regard unrelated donor marrow transplants as a new procedure, and in some situations experimental. Also, the expenses of an unrelated donor search and marrow collection tend to be significantly greater than the costs of the more limited procedures required for a sibling transplant. These facts have put transplant centers at considerable risk. Transplant centers have had to absorb significant increases in costs without knowing how much they will be reimbursed. For these reasons, transplant centers have had a difficult time in establishing their own charges (not knowing what the costs will be, or how much of the new costs will be "uncollectible").

To the extent that any "regulation" of transplant center prices needs to occur, this should be accomplished through negotiation and interactions between third party payors and transplant centers, as is the case with other treatment modalities. This will need to evolve over time and is not an appropriate activity to be coordinated either by NIH or the NMDP.

17. Senator Hatch: Has NIH met, or will it in the future, meet with private insurance companies to encourage them to consider broader coverage of both transplants and searches for donors? If not, why not?

Dr. Graves: Recent studies indicate that a marrow transplant is at least as cost effective as more traditional forms of therapy for some blood diseases. For other conditions, alternative therapy may not be available.

NIH, a research organization, does not have much interaction with third party payors. To our knowledge they have no "agreements" with insurance companies (similar to HCFA) and since federal contract funds are not to be used to subsidize patient care services (other than direct payments for HLA typing) provided by hospitals, the NIH has no apparent mechanism or leverage for influencing insurance companies.

The NMDP, in concert with its member centers, has developed and is implementing a plan to educate insurance companies and other third party payers about the clinical efficacy of unrelated donor marrow transplants. This effort involves meetings with major insurance plans, providing current information to technology assessment panels and publishing a report on the current status on unrelated donor marrow transplantation.

Increasingly, insurance companies and other third party payers have recognized the efficacy of unrelated donor marrow transplantation, providing coverage for at least a portion of the costs associated with this procedure. The Blue Cross-Blue Shield Association, Medicare, CHAMPUS and many state Medicaid programs now provide coverage for unrelated donor marrow transplants.

A survey of NMDP participating transplant centers, conducted in the fall of 1989, suggested, however, that tremendous variability exists among insurance companies as to whether coverage will be provided for certain services essential to performing an unrelated donor marrow transplant. Many centers reported that services associated with patient-directed HLA-DR typing, related lab tests and the medical evaluation of prospective donors are routinely denied. A number reported claims also being denied for the harvesting and transport of marrow even though coverage might

be provided for the actual transplant and follow-up care. (Unrelated donor expenses usually are about 10% of the total cost of a transplant. The majority of the costs are associated with the engraftment period.)

Of course, the failure to provide coverage or a severe limitation of benefits results in the shifting of transplant costs to the patient or patient's family. This is devastating for a family, already rocked by the emotional trauma of a life-threatening disease.

NMDP continues to make every effort to offer information and seek open communication with third party payors?

18. Senator Hatch: We have heard that donor centers have inadequate resources to cover the costs of blood typing. Please comment on the feasibility of making federal funds available for this purpose. How much would it cost and would the cost be justified by potential benefits?

Dr. Graves: For NMDP's fiscal year beginning May 1, 1990, $810,000 has been budgeted to five of NMDP's 70 donor centers for recruitment of blood donors as NMDP volunteer donors. Many more centers could efficiently recruit marrow donors through the same process if more funds were available. NMDP has been pleased with the effectiveness of this process for recruitment.

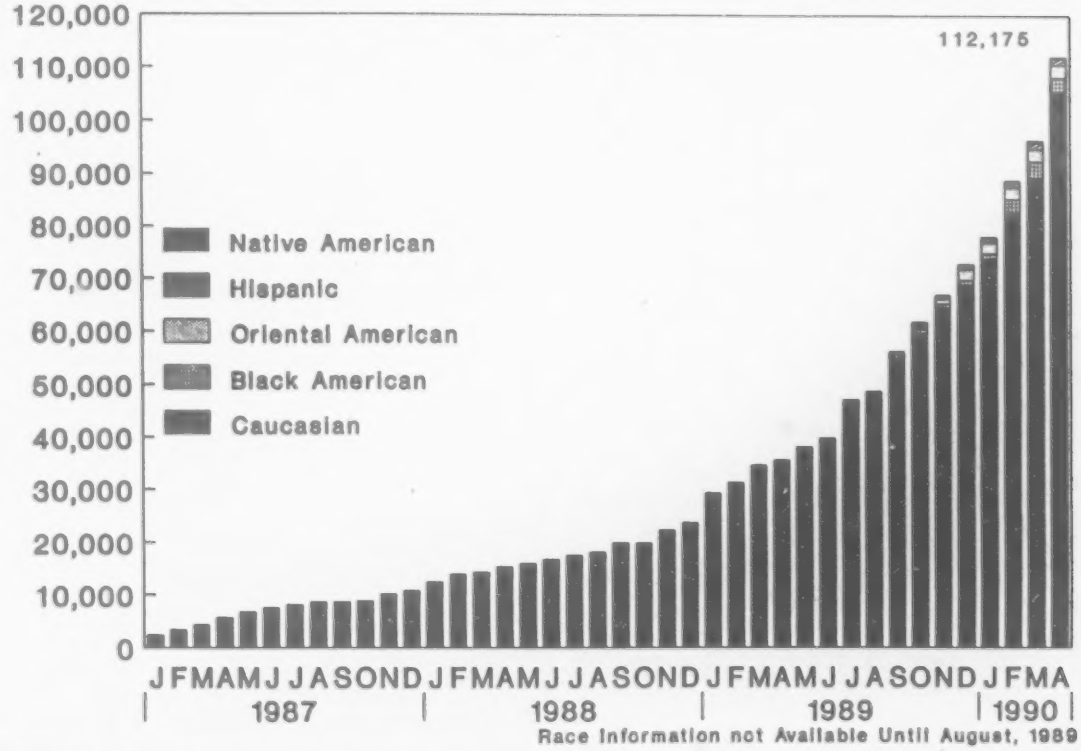
It should also be noted that many donor centers have stretched beyond reasonable limits to try to accommodate the growth of the Program and respond to potential volunteers. Many centers have long waiting lists of potential donors; some have stopped taking names. Lab personnel have donated thousands of hours and yet, many donor center labs are facing huge deficits in costs from HLA typing. For example, Puget Sound Blood Center, without including overhead, reports a $125,000 deficit for typing of NMDP donors and has another 1500 samples frozen (volunteers who have given blood samples not yet HLA typed or added to NMDP's registry to be searched by patients), waiting for more funds to become available internally or externally.

While the rapid growth of NMDP has strained many donor/blood centers, it should be noted that many of the centers have also seen a dramatic increase in platelet and blood donors from volunteers first recruited for the NMDP. This is surely one of the most positive side effects of the Program.

As the NMDP has reported on numerous occasions, the ability to attract new donors willing to have their names added to the registry has not been a problem. On the other hand, raising sufficient funds to *completely* HLA type new donors has been difficult. The challenge to raise contributed dollars to support typing, while supported actively by the NMDP, its recruitment organizations and donor centers, unfortunately falls too often on the shoulders of parents and others. NMDP estimates that approximately $32 million -- in today's dollars -- is necessary to increase the size of the registry to our next goal of 250,000 volunteer donors. A registry of this size, multiplied by cooperative relationships with other countries, will be necessary to begin offering the hope of a matched unrelated donor to significantly more patients in need than is now possible.

(Please see Attachments G & H, NMDP system resources and goals.)

VOLUNTEERS WILLING TO DONATE MARROW



Race Information not Available Until August, 1989

Source: National Marrow Donor Program
April 24, 1990

Attachment A

Attachment B

Heart of America Bone Marrow Donor Registry, Inc.

April 21, 1990

The Honorable Vic Fazio
United States Congress
Washington, DC 20515

Dear Congressman Fazio,

I have just completed my [illegible] the Office of Technology Assessment (OTA) report entitled, "Unrelated Bone Marrow Transplants in the United States: Policy Issues from a Patient Perspective". [illegible] comments are enclosed.

The OTA report contains many inaccuracies which I have attempted to describe in my comments. However, the report did help me better clarify the issues which separate the National Marrow Donor Program (NMDP) and the American Registry (AR). The principal issue concerns focus and its attendant problems.

Heart of America BMDR was established as a memorial to Jeffrey Harris, whose picture you see on this page. We at Heart of America BMDR understand the patient's perspective. When we began our journey into unrelated bone marrow transplantation [illegible] years ago, there were no donor centers and the NMDP was still a dream. Our 16 year old son faced all the obstacles finding a donor can present and he died before a donor could be found.

The American Registry is clearly patient focused. They clearly desire the patient perspective and they have established procedures to ensure that perspective is primary. As a founding member of the American Registry, Heart of America BMDR is very familiar with the arguments supporting that focus. However we became increasingly uncomfortable with that focus and, nearly 18 months ago, decided to terminate our association with the American Registry and affiliate with the National Marrow Donor Program.

Our decision [illegible] NMDP was based on our concern for the donor. [illegible] embraces the cause of the patient, the donor's interest is often overlooked and the risks minimized. We at Heart of America BMDR know the value of the donor's gift. We want to protect the donor's interest. It

P.O. Box 9651
Raytown, Missouri 64133

is a truly remarkable gift which donors provide, the gift of life. We must ensure that the donor is provided ample opportunity to understand the process which he or she is agreeing to undergo. We must minimize any risk to the donor and ensure that the donor is in good health. The donor deserves the right to make an informed decision without coercion. It is for these reasons that Heart of America BMDR believes that all donor centers must adhere to the standards developed by the National Marrow Donor Program.

I believe that the solution which will eliminate the differences between the National Marrow Donor Program and the American Registry include the following: all donor centers participate in the National Marrow Donor Program to ensure a donor focus; a patient advocacy function be established to ensure a patient focus; and, a forum be established to ensure public discussion of issues.

Congressional support of the National Marrow Donor Program has been essential to the growth of unrelated bone marrow transplants in the United States. Without that continued support we could not function as we do today. Heart of America BMDR, as the largest donor center in the United States, is very aware of the increasing business issues which require financial solutions. We have provided 14 donors in the past several months, a number that will continue to grow. It would be a significant tragedy to allow the patient focus of the American Registry to detract from the success of the NMDP and the more than 300 patients who have been provided the gift of life through the NMDP.

If you have any questions, you can reach the Heart of America BMDR at (816)333-0305.

Sincerely,

Frederick J. Harris
President

Enclosure

HEART OF AMERICA BONE MARROW DONOR REGISTRY

Comments on

Office of Technology Assessment Report:

"Unrelated Bone Marrow Transplants in the United States: Policy Issues from a Patient Perspective"

Ref:	Comments:
Page 2	The American Registry is identified as having 28,500 donors. The NMDP has monthly status reports identifying the number of donors per donor center. I believe the AR figure is too high and should be substantiated as is the NMDP figure.
Page 2	The AR is identified as having direct access to 100,000 donors in foreign registries. This is also true for the NMDP. However, the NMDP has formal agreements with several international groups with several more in the development stage.
Page 2	It is stated that there are US medical centers that perform bone marrow transplants but are not currently approved by the NMDP. Is this number significant? Have they applied and been turned down? This statement is anecdotal without more detailed information.
Page 2	It is stated that the medical center determines how the search will be conducted. In reality, the patient, the primary care physician, and the transplant center work collaboratively to find a donor. Speaking from my own experience, we (my wife and I) determined how we would search. It is clearly incorrect to state that the transplant center determines this activity.
Page 2	It is stated that the price of searching varies by transplant center even though the transplant center is "minimally involved. This statement is patently false. The author clearly has no understanding of the services provided by the transplant center. Most transplant centers have staffs dedicated to coordinating their patients' search activities which include: obtaining information required for processing the search; coordinating with insurance carriers; processing the weekly search updates and DR typing results; coordinating MLC samples; coordinating marrow collection and delivery; providing billing information; and, a host of other related activities. To state that these services

are provided by the NMDP or AR is simply inaccurate.

Page 3 The statement which begins, "In some cases, the difference..." is pointless.

Page 3 It is stated that finding a matched donor must require less than a heroic effort. In fact, most transplants do require less than a heroic effort. But for some patients, it will always be the case with current technology that a heroic effort will be needed. We are still early in the development of a national resource. Most of our donors are involved because of patients sharing their needs. It takes a clearly demonstrated need to motivate most people to consider the type of contribution that we are requesting. Heroism is not necessarily a bad thing. In my own experience, going to the public to find a donor for our son was a very positive experience in the midst of very difficult days.

Page 5 It is stated that the AR immediately accesses the foreign registries. I do not believe this is a true statement. The Anthony Nolan requires a search fee as do some of the other European Registries. The search is only completed when the AR submits the search fee. Both the NMDP and AR have essentially the same issues to deal with in Europe. The NMDP is working with the European Registries to automate the search process without the associated search fees.

Page 6 Again it is stated that the three major foreign registries are simultaneously searched. That is not true.

Page 6 The second paragraph discusses the differences in transplant center criteria. As a service to patients and physicians in our community, Heart of America provides information on differences in transplant criteria, some of the options available, transplant literature, available resources (including the AR), and other important information. The primary care physician is the appropriate place for this information to come together. It is inappropriate to ask a transplant center to refer patients to another protocol when that center may not agree with the other protocol. But in practice, patients are often transferred between transplant centers. Perhaps the NMDP should formalize this process.

The appropriate place for this type of counseling

is the NMDP and not the transplant centers. The NMDP is taking steps to create a patient ombudsman position.

Page 6 It is stated that some patients have had matches acceptable to unapproved centers but unable to secure the donor. This is not true. Since only approved transplant centers can access the NMDP, only they would know the existence of potential donors who match their criteria. Since this information is not provided to anyone else, it is not possible for a patient to know of the existence of a donor who might match an unapproved center's protocol.

Page 6 The anecdotal information concerning the "six antigen" match is false. Since the author tells us that the donor required DR typing, then a six antigen match is not possible since a six antigen match would include DR typing. Perhaps the author could explain this situation. The patient has no way of knowing that such a donor existed if it is in the NMDP. In addition, the transplant centers do not have access to donor center files.

While the patient's desires are an important part of the process, there are 28 approved centers from which to choose. Certainly the majority of patients will require some inconvenience in choosing an approved center. Such choices are not unreasonable when the purpose of approving centers is considered. Most parents desire the best of care for their children. The approval process of the NMDP ensures that the center meets minimal standards for non-related transplants.

Page 7 It is stated that a patient need not be affiliated with any particular transplant center to initiate a search with the AR. In fact, a patient can initiate a search with the AR. The patient is then aware of the existance and, in many cases, the location of the donor. This is clearly a violation of the donor's right to privacy. It is also an intrusion on the donor's right to make an informed decision without coercion. Heart of America has been contacted very recently by a patient whose search is being coordinated by the AR who wanted to DR type potential donors.

Clearly, the patient is not in a position to determine whether a transplant is appropriate. In very many cases, the primary care physician is not equipped to make that determination. In general, a patient is referred to a transplant center and that

center will determine the patient's eligibility for their centers transplant protocol. Therefore, it is the transplant center that should initiate search requests. The problem of delays in searching for donors often lies with the extended delay in referring patients to transplant centers. Primary care physicians can best service their patients by making immediate referrals at diagnosis-- even though the final decision may not include transplantation.

The AR's method of searching still leaves the patient with the problem of finding a bed in time, determining the appropriate transplant center based on the best available match, and all the other issues that are involved with this selection.

Page 8 The figures used by the author (ie, 20 US transplants and as many as 110 in foreign countries) are simply false. The AR's figures for foreign countries account for nearly the total of all transplants completed outside the US. Since most of the donors have come from the Anthony Nolan for transplants in England, this information is merely anecdotal.

In the US, the NMDP has found donors for more than 300 patients in slightly more than two years. The AR's figure of 20 in four years is the appropriate comparison. Heart of America's experience is significant. In three years as part of the AR, we completed three transplants. In the past six months with NMDP, we have completed 11 transplants with 10 more donors in final workup. The reasons are many but not least among them is the expeditious method of finding the donors and the services that NMDP provides. With 24 hour response to search requests, the transplant center is positioned to counsel their patients very quickly.

Page 8 The author states that Heart of America joined the NMDP during the past year. Our letter of agreement with NDMP was signed in December 1988. That agreement was the result of nearly a year of working out details and becoming familiar with NMDP operations. The NMDP was most courteous and helpful during this entire process. The NMDP has its own problems and several will require national level solution, but the program is working very well as evidenced by the volume of transplants being performed now - 25 per month.

The New Jersey Registry joined the NMDP in February, 1988.

Page 8 The author states that the procedures in both the NMDP and the AR are similar and require about four months to process a search from end to end. This statement is not true. The procedures are very different and the NMDP has provided several donors in far less time than four months. Once again the author has stated as fact information for which he has no substantial evidence. One of the most important reasons for our decision to affiliate with the NMDP was the difference in procedures. The NMDP is clearly donor focused and its procedures protect the interests of the donor. The NMDP transplant center procedures ensure the best of care for the patient. The AR is clearly patient focused. As donor centers, we must be donor centered. The transplant centers are the natural advocates for the patient. While a patient ombudsman is appropriate for the NMDP (and one will soon be appointed), there must exist natural advocates for all parties involved in the process.

Page 8 The author states that a minority of donors in both AR and NMDP are DR typed. This is a comparison of apples to oranges. The NMDP has more DR typed donors than the AR has donors. In several cases, patients have found exact matches on the initial search. While the number of DR typed donors must expand in order for the process to become more effective, the NMDP is DR typing several thousand donors each year. In fact, Heart of America has DR typed more than two thousand donors during the past 14 months as part of the NMDP (while DR typing only 400 donors in the previous four years as part of the AR).

Page 9 The author states that the AR will continue with formal evaluation based on the attending physician's determination. In most cases, the attending physician is not qualified to determine if a patient is a transplant candidate. In many cases the attending physician knows that transplantation is the therapy of choice, but the transplant center will make the determination of eligibility.

Page 9 The author states that DR typing requires 304 weeks in the NMDP and 2-6 weeks in the AR. While the NMDP figures are average, the AR figures are misleading. The NMDP tracks the time required for DR typing. Perhaps the AR can produce comparable tracking figures to substantiate the 2-6 weeks. There are several cases in which the AR has been more than a year in obtaining the required DR typing.

Page 9 The author states that in the AR, the patient's transplant center arranges for marrow procurement. This is clearly a conflict of interest. In the NMDP, this is not allowed. Only approved harvest centers can procure marrow. This is done to protect the rights of the donor and to ensure that the donor is no being asked to take unnecessary risks. To allow the transplant center, which will benefit through a procedure which costs more than $100,000 to provide appropriate counsel to the donor is, in my opinion, an unethical situation. Heart of America's Medical Director counsels all prospective donors including a medical evaluation of the donor. Our Medical Director's primary concern is for the donor.

Page 10 It is stated that all NMDP approved transplant centers require demonstration of insurance coverage or an ability to pay before a formal search is initiated. The AR also requires the same. The difference is in terminology. The AR requires, for the most part, payment for DR typing before the typing is completed (or approved insurance coverage). That is essentially the same as the formal search in the NMDP.

Page 11 It is stated that the infectious disease marker is performed by the transplant center. The infectious disease marker is performed by the donor center.

Page 11 The author states that charges are levied against the transplant center which passes these along to the patient with a small administrative fee while others add on thousands of dollars. This statement is extremely inaccurate and misleading. As stated elsewhere, the transplant centers provide several services for their transplant patients. The patient is billed for these services. While the NMDP Coordinating Center provides many services, they do not provide the same services as the transplant center. For example, the NMDP does not perform MLC's, coordinate with patients to ensure blood is available for testing, coordinate with insurance companies for same, track results by donor, or many other transplant related activities. At some transplant centers there may be 400 or more patients for whom searches are in progress. Clearly, tracking all of the patients and the search results and coordinating the activities associated with finding a suitable donor are complex and time consuming and the transplant center must be reimbursed for such activities.

Page 12 The author provides examples of the fees charged by

transplant centers and uses the term administrative costs. First, the so-called administrative costs are fees for services. Second, the variation in transplant center charges is reflective of different patient loads, different services provided, and the uniqueness of that center's billing system.

Page 12 Throughout the discussion of patient costs related to NMDP searches, the author uses the term administrative fee. I object to this term inasmuch as it suggest a fee for which services are not performed. That is not the case as is described elsewhere. The fees charged by transplant centers above and beyond the NMDP fees are for the services provided by the transplant center.

Page 13 The AR's charge of $300 for any search is significantly higher than the free preliminary search provided by the NMDP. While the AR charges $175.00 per DR typing, the quality of the DR typing must be addressed. The laboratories used by the AR for DR typing are not ASHI accredited and their error rates and ability to obtain splits are inferior to the NMDP contract laboratories. While the cost may be initially lower, the cost in lost time when typing is incorrect could be lost lives.

The harvest associated costs of the AR do not include the services provided by the NMDP. In addition, the harvest costs vary significantly by area of country. If only 20 transplants have been completed over the four years of its existence, I must question the validity of the figures (especially since the AR sends the donor off to the transplant center for harvest). While, in the final analysis, the cost may be lower through the AR, it cannot outweigh the services provided by the NMDP for the donor and the patient.

The statement that the AR requires that no administrative fee be added by the transplant center is untrue. The transplant center, as described elsewhere, performs a variety of search related services and they will charge for those services regardless of what the AR claims.

Page 13 The author states that permanent centers are logically blood centers. This statement is not true. Heart of America is the largest single source of donors in the United States and is not a blood center.

Page 14 It is stated that donor centers are now interested

in recruiting donors but have no money for typing. However, the NMDP has grown significantly in the past year (by 70,000 donors). Funding for this typing has come through fund raising activities, foundations, and payment by donors. It is a major misconception that families of patients pay for these typings. In several cases, families do contribute but the most significant portion of funding comes from outside the families. For example, we just completed a donor drive in Chicago which resulted in 1455 new donors being added to the NMDP. The cost of all typing is being paid for by a US corporation. In fact, nearly all of Heart of America's 17,000 donors have been typed through contributions of the type mentioned above.

The need for federal funding for donor recruitment is a very different issue than described by the author. There is significant public concern that the NMDP reach its goal of 250,000 donors rapidly and to DR type those donors. To do this in a short time frame will require funding above that which we can obtain with the fund raising methods currently used.

Page 15 Contrary to the statement that donors are also asked to become part of the national registry, Heart of America requires that potential donors become part of the NMDP. We simply will not type a person who wishes to become a donor for a specific patient. When such cases arise, we will help make arrangements for that person so they can be typed, but will not include them in our community drives nor pay for their typing.

Page 15 The author states that the major beneficiary of the LifeSavers sponsored drives is the NMDP itself. I find this statement to be irresponsible. Clearly, the major beneficiary of LifeSavers sponsored drives are the thousands of patients who need a bone marrow transplant.

To claim that the patient may bear the cost of a donor drive is to distort the entire process. Patients and their families do contribute significantly to this process. Their presence helps ensure that people will respond. They are actively participating in a war against their disease, which may be the first positive experience many patients have. That was certainly true when we were looking for a donor for our son. By the way, we did not spend a single penny of our own money on typing donors.

Page 15 The last paragraph lists some of the potential problems with community drives. To say that the world is not perfect does nothing to improve it. We have experienced many of the problems identified but we have learned how to overcome them. Our donors are well informed, the screening is effective, and they are not signing up for a specific patient. The issues described are simply problems which can be solved and are being solved.

Page 16 The author states that the financial burden falls on the private sector and specifically, on patients and their families. This statement is true in that the private sector is the source of funds for typing but it is patently untrue that the burden falls specifically on patients and their families. In the case of Heart of America, more than 90% of all contributions for typing have come from sources other than patients and their families. Perhaps the author can provide more detail on his information sources. (Perhaps the more important issue is that patients and their families should not have to assume more than their share of the burden.)

Page 16 The author states that transplant centers can only effectively serve patients with chronic illness and not acute leukemias. This is a false statement. While the lack of DR typing can adversely impact a potential transplant, it is only one of the problems. Initiating searches for diseases which can be effectively treated by transplantation early in the disease course continues to be a major problem. Patients are being referred to transplant centers only when all else fails. Patients are less than good candidates for transplant when that happens. In an ideal world, the search would begin immediately (preliminary search) when a patient is diagnosed (or early thereafter). Acute leukemias are being transplanted through the NMDP. All of us would like to see more DR typed donors. The process will work much better and be faster if that were true. We are looking at different ways to obtain that goal.

Page 18 The author states that the public may be expecting the NMDP to be performing a patient advocacy role and, further, that the AR is clearly in the patient advocacy role. First, does the public expect the NMDP to serve the role as patient advocate? I do not believe this is the case. But I do believe that the public expects a patient service function (ie, information, help with problems, etc.). The AR's position is, in my opinion, a clear conflict

of interest. The AR recruits donors, matches them with patients and delivers the donor for harvest all from the patient's perspective. The donor faces risks and is expressing a significant desire to perform an altruistic function. It is the donor who needs to be protected. It is the donor who needs an advocate. Who cares for the donor in the AR? Should that be left to an organization that is clearly in the patient advocacy role? It is my opinion that the AR should not be allowed to handle donors at all. They want to be in the patient and of the business and should move in that direction. Those of us who see the need for a strong donor centered organization should be in the business of caring for donors.

Page 19 The author's concluding remarks miss much of the differences which separate the NMDP and the AR. In American medicine, the primary care physician has always assumed the role of advocate for the patient. There are problems with that process as there are in all human endeavors. It is support of the primary care physician that needs attention. That physician should be positioned to know what resources are available and the differences in available treatments. The American Cancer Society is working on those problems as is NIH. In the business of bone marrow transplantation, there are many problems. One of those is an adequate source of donors. The NMDP has done and continues to do an exemplary job of recruiting new donors. Another problem is coordinating between those performing transplants and the donor sources. Again, the NMDP has done an exemplary job of coordinating those activities. Still another problem is providing services to patients who want or need additional information or who have grievances with the process. The NMDP is only beginning to deal with this problem.

To confuse the issues by suggesting that the financial and philosophical differences of the AR and NMDP must be resolved is to miss the basic issues which separate them. The NMDP is a large national organization with more than 100,000 donors performing 25 transplants per month. The operations of such an organization are significant. Those operations and services must be paid for by those they serve. The AR has been, for the most part, a volunteer based group without the costs associated with the NMDP. However, they do not provide a significant service as evidenced by the number of transplants performed (20) in a four year period. The AR is a small organization (about

15,000 donors in member donor centers) performing a relatively small number of searches (7-10 per week). It is a slow process compared to the NMDP's 24 hour response. DR typing requires the same slow response in the AR as compared to NMDP. The two largest donor sources (28,000 donors) in the AR have left that organization because of their concern for the donor.

Finally, from the patient's perspective, and I have been the parent of a teenage patient, what is really needed is a system that works, that will yield a donor when a patient needs a transplant. Like of much of medicine, it costs too much. But the alternative is death. Give me something that works.

Attachment C

Heart of America Bone Marrow Donor Registry, Inc.

April 27, 1990

The Honorable Edward Kennedy
315 Russell Senate Office Building
Washington, DC 20510

Dear Senator Kennedy,

I am writing to express my concern with some of the issues that have been raised by the American Registry at a hearing of your committee a few weeks ago. Clearly, America is best served when many voices are heard in a public forum. Your participation in this process is most welcome. And, as a native son of Massachusetts, I encourage your scrutiny.

There is, however, some misinformation which I would like to bring to your attention. First amongst these is the overriding issue which separates the National Marrow Donor Program and the American Registry. On Tuesday evening of this week, my wife and I met a donor and his mother at the airport in Kansas City. The donor is from out of town and had come to Kansas City to be harvested (that is, become a bone marrow donor). After we had admitted the donor to our harvest center and driven his mother to the hotel, my wife observed that these people had shown enormous faith in us and our program. They were willing to come here, away from home, to be under the care of strange people and undergo a significant procedure. Heart of America BMDR is dedicated to caring for donors. As the parents of a child who succumbed to leukemia, we recognize the wonderful gift which donors provide.

The American Registry takes the patient's perspective. They are organized and have developed procedures which ensure the patient focus. We believe that focus is inappropriate for the care and management of donors. While I personally commend the American Registry on their goals, there must be a distinction between patient focus and care of donors. It is at best an unethical situation to ask people to volunteer for the donor program and then not provide the safety and care appropriate for the donor. The American Registry simply turns the donor over to the patient's transplant center, a center which will benefit by some $200,000 or more for performing the transplant. Clearly, that center is not the best place for the donor to be. The potential for harm to the donor has been magnified, and while most men are honorable, the temptation should never exist.

P.O. Box 9551
Raytown, Missouri 64133
816.111.5104

The Medical Director of Heart of America BMTR is focused on the donor. He will argue the donor's case against the transplant center and their case for the patient. This natural advocacy for patient and donor is healthy.

I believe it would be unwise to support the American Registry as long as they recruit donors and do not have the safeguards in place to protect the donors. I speak from my own experience as one of the founding members of the American Registry and the first to join the National Marrow Donor Program. Our concern for the donor has been echoed by the New Jersey HLA Registry which has recently left the American Registry to join the National Marrow Donor Program.

Lastly, service to patients is best measured by the number of patients served. The National Marrow Donor Program has yielded more than 350 transplants in the United States in 30 months compared to the 20 transplants involving the American Registry in more than four years.

As a national resource, the National Marrow Donor Program is young. It requires the scrutiny of Congress and the American public. There are problems which need to be discussed openly. At the same time we must base our discussions and criticisms on facts. The patient perspective sometimes clouds the issues because we are all advocates for those who suffer. When our son, Jeff, was sick, we wanted something that works and there was nothing. Along with Bob Graves and others we have worked to change that. We have worked these past several years to build a program which all of us can embrace. Your assistance in making the program still better is requested. I would be most happy to work with your staff on any of the issues which have been discussed above or to provide you any additional information you may desire.

Sincerely,

Frederick J. Harris
President

cc: Ms. Darrell Jodrey

Attachment D

AMERICAN ASSOCIATION OF BLOOD BANKS
Suite 600, 1117 North 19th Street, Arlington, Virginia 22209 (703) 528-8200 FAX: (703) 527-8038

April 25, 1990

Admiral E.R. Zumwalt, Jr.
Chairman, Board of Directors
National Marrow Donor Program
1500 Wilson Boulevard
Arlington, VA 22209

Dear Admiral Zumwalt:

I am writing to reaffirm the AABB's position that the confidentiality of individuals recruited as bone marrow donors must be preserved. It is our view that patients and their families should not have information that allows the donor's identity to be revealed. Similarly, we feel strongly that the donor's safety must be preserved, and that centers that collect bone marrow must be qualified and accredited to harvest marrow.

The AABB will only support marrow donor programs that provide such donor confidentiality and safety.

Very truly yours,

Toby L. Simon

Toby L. Simon, MD
President

cc: Doug Shaw, Executive Director
National Marrow Donor Program
Charles Wallas, MD

Attachment E

CCBC
Council of Community Blood Centers

Suite 700 • 725 15th Street, N.W. • Washington, D.C. 20005
(202) 393-5725 • FAX (202) 393-1282 • MCI ID 350-2208

April 25, 1990

Admiral E.R. Zumwalt, Jr. (Ret.)
Chairman
National Marrow Donor Program
1500 Wilson Blvd.
Arlington, Virginia 22209

Dear Admiral Zumwalt,

As you are aware the National Marrow Donor Program was created under the guidance of the Council of Community Blood Centers in conjunction with the American National Red Cross and the American Association of Blood Banks. Currently 9 of 37 CCBC members participate as NMDP donor centers. Over 16,000 donors in the registry are associated with CCBC centers.

Our organization continues to strongly support the goals of the NMDP. We support the principles of donor advocacy on which the Program was developed and would be opposed to changes that would not be in the best interest of the donors. We could not support changes in the standards of the Program that would reduce the commitment to donor confidentiality or increase donor risks.

We also remain committed to the principle of restriction of access to registry donors to approved transplant centers only. The approval process assures that transplant centers use protocols that expose donors to the risks associated with marrow extraction only when there is probable benefit to potential recipients. Such oversight is necessary to balance donor and patient advocacy.

Our members feel the obligation of the NMDP donor centers is to inform, protect and serve the donors. Our members also accept a responsibility to respond to NMDP requests to arrange potential donor testing and counseling in a timely, efficient and thorough manner.

We feel the Program has been very successful since its creation because of adherence to the founding principles. We continue to support the Program and its principles.

Sincerely,

Robert G. Chapman/for

Robert G. Chapman, M.D.
President

Attachment F

The Bank Account

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National Organ/Tissue Donor Awareness Week

Bruce Conway
Executive Director

The week of April 22-28 will be a very special week for you, our wonderful members. It has been designated National Organ and Tissue Donor Awareness Week. Although the number of transplants has increased each year there remains a tremendous need for additional donors. In our Fall 1989 newsletter we printed the latest transplant statistics with 16,980 persons awaiting the transplant of vital organs – these statistics do not include those persons needing cornea, bone marrow or skin. We must reverse these numbers so that no person will die waiting for a second chance at life! Won't you please become Ambassadors for a week for The Living Bank to help us identify, register and inform more organ and tissue donors. Who is more qualified to increase our donor members than those already registered to give the Gift of Life. If each of you tell just three friends or co-workers about the importance of organ donation and those individuals in turn become members of The Living Bank, what a wonderful difference it will make! Let's all work together during the week of April 22 to educate Americans on their opportunity to bring life to others and triple the number of Living Bank members during this very special week! Those interested may call toll-free 1-800-528-2971 or write Box 6725, Houston, Texas 77265.

Bone Marrow: The Living Gift of Life

In response to many inquiries about bone marrow donation received from Living Bank members, we have reprinted the following article from The National Marrow Donor Headquarters.

The National Marrow Donor Program is an exciting new medical option for patients suffering from leukemia, aplastic anemia and some other blood disorders. NMDP is a federally funded, international effort to build and operate a registry of volunteers willing to donate bone marrow, if matched with a recipient needing a transplant. The chance of finding a donor who matches a patient's tissue typing is estimated at one in 20,000.

Two year old Shaina, shown with her family, received an unrelated marrow transplant as a baby and her mother was an unrelated donor last winter.

15-20 unrelated bone marrow transplants are currently being performed each month in the United States. NMDP donor searches began in the fall of 1987. The first transplant was performed in December 1987, the 100th in March 1989 and the 200th in October of 1989. NMDP has now facilitated over 230 transplants and some from the very special contributions of its volunteers.

In an effort to offer hope to more Americans, NMDP continues to broaden its appeal for donors. The larger the donor pool, the better chance of finding "the living gift of life", the miracle match for every patient.

Volunteer donors must be in excellent health and between the ages of 18 and 55. After a simple blood test, the donor's typing is entered in the NMDP computers. If found to be the miracle match, the donor is asked to give of his time and comfort for a few days to offer the living gift of life to a special person, somewhere in the world, whose typing he matches.

Marrow is aspirated by needle from the donor's hip. It will be replenished by the body in about two weeks. The retrieved marrow is immediately transported to the patient's location and given to the patient like a blood transfusion. The patient has been undergoing extreme chemotherapy to deplete diseased marrow. During the four to six weeks following the transplant, the new marrow regenerates itself, filling the patient's bones with healthy fluid, which fuels a new system of non-diseased blood. Preliminary blood typing tests cost around $75 and NMDP is also soliciting private funds to assist with the cost of typing those willing to become marrow donors. Donor recruitment groups, patient families and friends have all become involved in working to raise the funds necessary to add more volunteers.

One NMDP staff person wrote "it is difficult to describe the excitement and hope we have given to some families who had a loved one diagnosed with a fatal illness. I wish I could show you Patrick's high school graduation picture or arrange for you to meet two-year old Shaina and her family –or Pamela, the mother of two young children. All of them were unrelated marrow transplant recipients who are alive today because of the new hope which has come from advances in medical technology and from the generous spirit of so many individuals around the world."

Along with donor searches, NMDP is involved in research efforts. New insights regarding blood disorders may be the result of these activities.

For more information about the NMDP program, location of testing centers or how you can become marrow donor, send a stamped, self-addressed envelope marked "Marrow Donor" to: The Living Bank, Box 6725, Houston, Texas 77265, or call National Marrow Donor Program, 1-800-654-1247; or Life Savers Foundation of America 1-800-960-1060.

Attachment G

THE PROJECTED COST OF HLA TYPING A REGISTRY OF 250,000 DONORS

National Marrow Donor Program

1. 150,000 additional U.S.A. donors are needed to reach the current goal of 250,000 donors.

2. The cost to HLA type 150,000 donors is as follows:

a. HLA-A,B testing @ $75/test*	=	$11,250,000
b. The incremental cost of HLA-DR testing done in conjunction with HLA-A,B testing @ $85/test**	=	$12,750,000
		$24,000,000

3. The cost to complete the DR testing of existing donors who are already HLA-A,B typed:** 71,000 @ $125/test = $ 8,875,000

4. The total cost to achieve a Registry of 250,000 donors who are fully HLA-A,B and DR typed = $32,875,000

*The cost of testing includes supplies, sample collection, shipping and laboratory services.

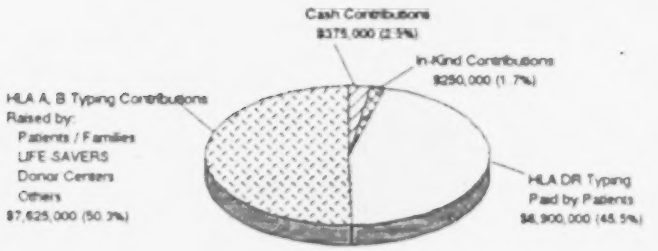
**Currently most volunteers are HLA-DR typed on request by Transplant Centers for specific patients. The cost to patients and third parties for this typing is approximately $280 per donor, far greater than the cost of completing this test at the time new donors are enrolled in the Registry.

April 20, 1990

Attachment II

NATIONAL MARROW DONOR PROGRAM SYSTEM

Estimate of Funds Raised in the Private Sector
To Support NMDP Activities
1986 - 1990



Note

1. Estimated total funds contributed $15,150,000.
2. Federal limitations on NMDP's ability to use contract and fee-for-service revenue for fundraising require that independent entities be established to carry on this activity.
3. Estimate does not include expenses associated with donor work up, marrow procurement and transport, or transplant services, or the thousands of volunteer hours which have been donated.

April 20, 1990

The CHAIRMAN. Thank you very much. The committee stands adjourned.

[Whereupon, at 12:46 p.m., the committee was adjourned.]